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April 26, 2024

VIA EMAIL and ECF
Hon. Douglas E. Arpert, U.S.M.J. (Ret.)
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102

Re: ***U.S. ex rel. Silbersher v. Janssen Biotech Inc.***
Civil Action No. 19-12107(MEF)(CLW)

Dear Judge Arpert:

Relator submits this letter pursuant to Civil Local Rule 37.1 governing discovery disputes and the Court's Order referring discovery disputes to the Special Master (ECF No. 331). The parties met and conferred on the issues raised in this letter on multiple occasions over the past few weeks, and most recently on April 23, 2024. The parties were unable to reach a resolution and are at an impasse. Relator therefore moves for relief to address Defendants' deficient responses to certain of Relator's most recent written discovery requests, as well as Defendants' refusal to provide a Rule 30(b)(6) witness for multiple topics noticed by Relator.

I. Defendants' Deficient Responses to Relator's Second Set of Interrogatories

As a preliminary matter, Defendants waived any objections to Relator's most recent set of written interrogatories by failing to respond within 30 days as required under Rule 33. Relator served his Second Set of Interrogatories on Defendants on February 15, 2024. Defendants' responses were due by March 18, 2024, but they failed to serve them on time. Instead, and without

any explanation for their tardy response, Defendants served a mix of objections and responses seven days late, on March 25, 2024.

As a result, Defendants have waived any objections to these interrogatories. *See* Fed. R. Civ. P. R. 33(b)(4) ("The grounds for objecting to an interrogatory must be stated with specificity. Any ground ***not stated in a timely objection is waived*** unless the court, for good cause, excuses the failure.") (emphasis added); *id.*, Notes of Advisory Committee on Rules–1993 Amendment ("Paragraph (4) is added to make clear that objections must be specifically justified, and that unstated or ***untimely grounds for objection ordinarily are waived***.") (emphasis added); *Allen v. Banner Life Ins. Co.*, 340 F.R.D. 232, 239 (D.N.J. 2022) (referring to Rule 33's "automatic-waiver provision governing interrogatories").

Although Defendants automatically waived their objections to all of Relator's Second Set of Interrogatories, Relator respectfully requests that Your Honor direct Defendants to serve responses without objections only to Interrogatories No. 16 and 23-25 at this time. *See Rohrbach v. NVR, Inc.*, 2022 U.S. Dist. LEXIS 160886, at *3-4 (E.D. Pa. July 8, 2022) (citing the waiver provision in Rule 33 in ordering that party provide "full and complete" responses to interrogatories "without objection"). The parties continue to meet and confer with respect to the remaining interrogatories.

Further, and as detailed below, Defendants' responses to Interrogatories No. 16 and 23-25 are wholly insufficient, regardless of Defendants' waiver of objections.

Interrogatory No. 16. This Interrogatory asks Defendants to describe "the roles, rights, and responsibilities of each corporate entity that participated, during the relevant period, in the research, development, manufacture, marketing, or sale of Zytiga."

After asserting a number of meritless objections, Defendants responded with a general description of how Johnson & Johnson is the parent company to the defendant Janssen entities, and stated that the "Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company."

Defendants further stated they were willing to meet and confer to "understand the information sought by this Interrogatory." During the parties' meet and confer, Defendants' counsel attempted to justify their deficient response by offering a hyper-technical reading of "roles, rights, and responsibilities," arguing that it was unintelligible or sought irrelevant information because it somehow was not tethered to the sale, etc., of Zytiga.

In response, Relator's counsel explained that the Interrogatory only (and obviously) seeks information about Defendants' (and any corporate entities') roles, rights, and responsibilities *as they relate to* the sale, etc., of Zytiga. Instead of offering to respond to the Interrogatory using that common-sense understanding, Defendants chose to stand on their objections and non-responsive response. Defendants offered no other justification for their objections to this Interrogatory or their refusal to provide information about what role each Defendant and any other corporate entities may have played in relation to the sale, etc., of Zytiga—information that is critical to the claims at issue.

Interrogatory No. 23. This Interrogatory asks Defendants to describe "the ownership, control, and corporate relationships between and among Defendants and their affiliates involved in the research, development, marketing, and sale of Zytiga, including, without limitation, how ownership in each entity is held and by which entity or entities." After asserting some meritless objections, Defendants responded that Johnson & Johnson is the parent company to the defendant Janssen entities.

Defendants' response is insufficient, including because it is non-responsive. Relator is entitled to inquire into the corporate relationships among the various corporate entity Defendants, as well as among any non-party affiliates that also were involved with the sale, etc., of Zytiga that the parent company used to exercise control over the operating entities that sold and marketed Zytiga, and which held the intellectual property and regulatory rights relating to the drug. For example, it appears that Johnson & Johnson uses intermediatory companies that are non-income producing cost centers that nominally employ executives who sit on cross-functional committees from multiple subsidiaries to coordinate the activities of, and exercise control over, the defendant Janssen entities in marketing and selling Zytiga in the United States. Relator is entitled to a clear answer from Defendants that sets forth the ownership, control, and corporate relationships between these various affiliated entities that all operate under the coordinated direction of Johnson & Johnson.

Interrogatories No. 24-25. These Interrogatories seek Defendants' legal and factual contentions relating to Defendants' delay of generic entry by obtaining, listing, and asserting the '438 Patent (Interrogatory No. 24) and the materiality of Defendants' exclusion of generic competition upon the government's (or Plaintiff States') decision to pay or reimburse for Zytiga (Interrogatory No. 25).[1]

After asserting a number of other meritless objections, Defendants objected that these Interrogatories are premature and improper because "discovery is ongoing, expert discovery has not yet begun," and "Relator bears the burden of proof." Defendants further objected that these Interrogatories "may be the subject of expert discovery." None of Defendants' objections are well

[1] Relator has attached to this letter copies of the discovery responses at issue.

taken; Defendants cannot duck their discovery obligations by effectively saying that they would rather not respond right now. To the contrary, Relator is entitled to a substantive response that provides Defendants' current factual and legal contentions regarding the important issues addressed by each of these Interrogatories.

Relator therefore respectfully requests that Defendants be ordered to provide full and complete responses to Interrogatories No. 16 and 23-25.

II. Defendants' Deficient Responses to Relator's Sixth Set of Requests for Production

Relator also respectfully requests that Your Honor order Defendants to further respond – and produce documents in connection with – Requests No. 88 and 89 of Relator's Sixth Set of Requests for Production.

Request No. 88. This Request seeks "[a]ll documents related to any agreements between two or more of the Defendants to provide indemnity, cover costs, or reimburse for any liabilities related to this action." Defendants have wrongfully refused to search for any documents responsive to this Request, asserting a number of meritless objections.

As Relator's counsel explained to Defendants' counsel, this Request reasonably seeks indemnity agreements between and among the Defendant corporate entities because the existence and terms of such agreements may reveal important information that establishes liability for one or more corporate entity or affects apportionment of liability among them for the claims asserted in this case. Defendants had no substantive response to this point, but instead merely stood upon their objections. Defendants should be required to search for and produce responsive documents.

Request No. 89. This Request seeks documents "concerning any contracts, agreements, or licenses between and among Defendants and affiliates of Defendants related to the development, research, manufacturing, sale, marketing, and distribution of Zytiga (including, without limitation, any rights to the '213 Patent and the '438 Patent). Despite the obviously important nature of the documents sought by this Request, Defendants again chose the path of misdirection by asserting a number of meritless objections, agreeing to meet and confer, and pointing to several previously-produced documents.

Defendants have not argued—in the parties' meet and confers or otherwise—that these few previously-produced documents constitute *all agreements* between and among Defendants and their affiliates relating to the sale, etc., of Zytiga, much less that they constitute all documents responsive to this Request. Defendants' response is wholly insufficient; they should be ordered to produce all responsive documents.

III. Defendants' Deficient Responses to Relator's First Set of Requests for Admission

Relator also respectfully requests that Your Honor order Defendants to provide amended responses to the following requests in Relator's First Set of Requests for Admission.

Requests No. 1-4. These Requests ask Defendants to admit that *each separate Defendant* "exercised control over the sale of Zytiga," a central issue as to the liability of each Defendant in this action. After objecting to the term "exercised control" as vague, etc., Defendants responded to Request No. 1 by admitting that "Johnson & Johnson sold Zytiga, including by and through its subsidiaries . . . ." Defendants responded to Request No. 2-4 (materially identical requests, but relating to each of the three remaining subsidiary defendants) by simply referring to their response to Request No. 1. For all these Requests, Defendants did not admit or deny the Requests.

Defendants' responses are insufficient, including because they are non-responsive. As to Request No. 1, Relator is entitled to have a straightforward response to the request he served – that is, Relator is entitled to know whether Johnson & Johnson exercised control over the sale of Zytiga. Defendants' admission that Johnson & Johnson sold Zytiga through its subsidiaries leaves room for Defendants to argue later that one or more of Johnson & Johnson's subsidiaries may have sold Zytiga, but Johnson & Johnson did not exercise control over those sales (or exercise control over its subsidiaries in making those sales). Defendants should be ordered to provide a straightforward response to this Request.

As to Requests No. 2-4, Relator is entitled to know whether each of the other Defendants exercised control over the sale of Zytiga. Defendants' response to each of these Requests that *Johnson & Johnson* sold Zytiga through unspecified subsidiaries is not responsive, both because Defendants have not answered whether each of the other individual corporate Defendants exercised control over the sale of Zytiga, and because Defendants have not even identified any specific subsidiaries through which Johnson & Johnson sold Zytiga. Defendants should be ordered to provide a response to each of these Requests.

Request No. 6. This Request asks Defendants to admit that they are "real parties in interest in the '438 Patent." After objecting to the term "real parties in interest" as vague, etc., Defendants responded to this Request by admitting that "Janssen Oncology, Inc. was the assignee listed on the '438 Patent." Defendants did not otherwise admit or deny this Request.

Again, Defendants' response is insufficient, including because it is non-responsive. As Relator has alleged, Janssen Biotech, Janssen Oncology, and Janssen R&D filed certifications that they were real parties in interest for the '438 Patent and that they were wholly-owned subsidiaries of Johnson & Johnson, which was also a party in interest to the '438 Patent application. (SAC ¶

67.) Relator is entitled to Defendants' position as to that allegation, through a straightforward admission or denial of the fact that *each of the Defendants* is a real party in interest to the '438 Patent. Defendants cannot avoid providing that information by providing a different answer (the identity of the assignee listed on the '438 Patent) as to only one Defendant, Janssen Oncology. Defendants should be ordered to provide a supplemental response.

Request No. 7 & 9. These Requests ask Defendants to admit that "Johnson & Johnson, Janssen Biotech, Janssen Oncology, and Janssen Research & Development collectively sell Zytiga pursuant to NDA No. 202379" (Request No. 7) and that "Johnson & Johnson arranged for the sale of Zytiga through its wholly owned subsidiaries, including the Janssen entities and their affiliates" (Request No. 9). After asserting meritless objections, Defendants responded to each Request by admitting that "Johnson & Johnson sold Zytiga, including by and through its subsidiaries . . . ." Defendants did not otherwise admit or deny these Requests.

Defendants' responses are insufficient, including because they are non-responsive. Stating that Johnson & Johnson sold Zytiga through unspecified subsidiaries does not answer whether Defendants collectively sell Zytiga pursuant to NDA No. 202379 (Request No. 7) or whether *Johnson & Johnson itself* "arranged for the sale of Zytiga" through its subsidiaries (Request No. 9). Defendants should be ordered to provide supplemental responses to these Requests.

Requests No. 11-14 & 16-20. These Requests seek Defendants' position regarding a number of important issues in this case. After asserting other meritless objections, Defendants objected that each of these Requests seek "admission of a legal conclusion." This objection is baseless. These Requests ask for *factual admissions* about each Defendant's knowledge of underlying facts. For example, Request No. 12 asked Defendants to "[a]dmit that during the prosecution of the '438 Patent, each Defendant knew that Zytiga held a material competitive

advantage against competitors, including, without limitation, XTANDI, because it had or was expected to have FDA approval before those competing treatments."

Even in the event these Requests implicated legal issues, Defendants' objections still would not be well taken because Rule 36 explicitly allows for requests applying law to facts or opinions about law and facts. *See* Fed. R. Civ. P. R. 36(a)(1) ("A party may serve on any other party a written request to admit, for purposes of the pending action only, the truth of any matters within the scope of Rule 26(b)(1) relating to . . . facts, the ***application of law to fact***, or ***opinions about either***") (emphasis added).

Defendants also objected that each Request calls for Defendants to "assume facts and conclusions that are not established by the record." Of course, the very purpose of discovery is to discover relevant facts, and Defendants cannot avoid their discovery obligations by asserting evidentiary objections that may or may not apply at trial. Relator is entitled to know if Defendants admit or deny that each of them had knowledge of the facts asserted.

Defendants' objections are untenable because they improperly obfuscate and render insufficient their subsequent denial of the Requests. Defendants should be ordered to provide a straightforward admission or denial to each Request without first asserting improper objections and then making their response subject to those objections.

IV. Defendants' Refusal to Provide Corporate Representatives for Rule 30(b)(6) Topics

Finally, Relator respectfully requests that Your Honor order Defendants to provide Rule 30(b)(6) corporate representatives for the below topics requested by Relator, for which Defendants have refused to provide a representative to testify.

Topic 12. In this topic, Relator seeks a corporate representative to testify to "[t]he roles, rights, and responsibilities of each corporate entity that is a direct or indirect subsidiary of Johnson & Johnson, including [the three Defendant Janssen subsidiaries], that participated in the research, development, manufacture, marketing, or sale of Zytiga."

After asserting a number of meritless objections, Defendants responded that they "will not produce a witness in response to this Topic, which is too vague, ambiguous, broad, ill-defined, and burdensome to properly prepare a witness."

There is no basis for Defendants' refusal to produce a witness to testify regarding this Topic, which simply seeks testimony explaining the roles of each Johnson & Johnson subsidiary regarding the sale, etc., of Zytiga. Defendants undoubtedly know the roles of the various Johnson & Johnson subsidiaries in bringing Zytiga to market; they should not be allowed to hide that information behind feigned ignorance regarding what this Topic is intended to cover. They should be ordered to produce a witness to testify on Topic 12.

Topic 13. In this Topic, Relator seeks a corporate representative to testify to the "role, rights, and responsibilities" of each Defendant relating to the '340 Application (for the allegedly fraudulent '438 Patent), the '440 Application (which was a discontinued application claiming the same inventions as the '340 Application), the '213 Patent (the original chemical compound patent), and the '438 Patent.

Again, Defendants asserted a number of meritless objections, then responded that they "will not produce a witness in response to this Topic, which is too vague, ambiguous, broad, ill-defined, and burdensome to properly prepare a witness." Defendants further objected that this Topic was duplicative of Topics 1 ("Defendants' prosecution of all applications leading to the '438 Patent, including the '340 and '440 Applications"), 2 ("Defendants' due diligence relating to the

Commercial Success Argument prior to submitting that argument to the Patent Office"), and 3 ("All facts, issues, and materials that Defendants relied upon or considered in making the Commercial Success Argument").

Defendants wrongfully refused to provide a witness for this Topic. Relator is entitled to inquire into the specific role(s) that each Defendant played relating to the referenced applications and patents, including because the testimony on this Topic may be necessary to establish one or more of the Defendants' liability for the claims in this action.

This Topic is not duplicative of Topic 1, which sought testimony about Defendants' prosecution of '340 and '440 Applications, but did not seek testimony about any individual Defendant's role in those applications and did not seek testimony relating to Defendants' post-prosecution roles relating to either of the patents at issue. Neither is it duplicative of Topics 2 and 3, which sought more specific information relating to the commercial success argument made during prosecution of the '340 Application. Defendants should be ordered to provide a corporate representative to testify to Topic 13.

Topics 15-16 & 19-20. In these Topics, Relator seeks a corporate representative to testify to:

- The "acquisition, license, or transfer of any Rights related to the '438 Patent" (Topic 15)
- Any "actions taken by Johnson & Johnson to enforce the '438 Patent, and any benefits derived by Johnson & Johnson" from such enforcement (Topic 16)
- Each Defendant's "expectations, goals, and strategy with respect to launching a coated version of Zytiga (Topic 19)

- Each Defendant's "expectations, goals, and strategy with respect to launching a 500 mg version of Zytiga" (the original was 250 mg) (Topic 20)

After asserting a number of meritless objections, Defendants responded to each of these Topics that they "will not produce a witness in response to this Topic, which is irrelevant to Relator's claims and too vague, ambiguous, broad, ill-defined, and burdensome to properly prepare a witness."

Contrary to Defendants' argument, these Topics are both highly relevant and straightforward in the subjects they cover:

- Topic 15 is important because it will reveal how rights related to the '438 Patent were held or transferred between and among Johnson & Johnson and its subsidiary corporate entities that were involved with Zytiga.
- Topic 16 is important to show what Johnson & Johnson (the corporate parent entity) itself did to enforce the '438 Patent and what benefits it obtained from that enforcement.
- Topics 19 and 20 are important because Defendants' launch of a coated version of Zytiga was intended to suppress generic entry in anticipation of losing the patent infringement litigation, and this information is highly relevant to Defendants' contemporaneous belief in the validity of the patent they asserted against generic competitors, as well as the amount of damages caused by their fraudulent scheme.

Testimony on these issues may help establish liability by one or more of the Defendants for the claims in this action, as well as the amount of damages. Defendants should be ordered to produce a witness to testify on both of these Topics.

Topic 18. In Topic 18, Relator seeks a corporate representative to testify about the sale of the authorized generic of Zytiga, including contracts, licenses, and control of the right to sell the authorized generic, as well as about Defendants' goals and expectations with respect to the sale of an authorized generic. Defendants have offered to provide a designee to testify only as to "the actual sales of Authorized Generics." Relator is also entitled to inquire into issues such as Defendants' control over the timing and amount of authorized generic sales, and the independence of the authorized generic manufacturer. This information is relevant to the potential variability of authorized generic sales given different but-for scenarios.

Topics 25 & 26. In these Topics, Relator seeks a corporate representative to testify to the "negotiation and terms of any settlement with generic competitors sued for patent infringement relating to Zytiga" (Topic 25) and the "negotiation and terms of any exclusive pharmacy agreements that was intended to, or had the effect of, maintaining or protecting Zytiga's market share against generic competition" (Topic 26). After asserting a number of meritless objections, Defendants responded to each of these Topics that they simply "will not produce a witness in response to this Topic."

Defendants wrongfully refused to provide a witness for these Topics. Relator is entitled to inquire into any settlements Defendants reached with generic competitors because they would implicate issues at the heart of this action, including whether and how Defendants used the '438 Patent to forestall generic competition. Likewise, Relator is entitled to inquire into any exclusive pharmacy agreements that Defendants used to protect Zytiga's market share against generic competition because such agreements are often used by brand companies to restrict access of generic competitors to distribution channels, suppressing generic entry.

Accordingly, Defendants should be ordered to provide a corporate representative to testify regarding Topics 25 and 26 as well.

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Based on the foregoing, Your Honor should grant Relator's motion.

Respectfully yours,

HERRERA KENNEDY LLP

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ATTACHMENT - DISCOVERY RESPONSES

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA; STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA, *ex rel*. ZACHARY SILBERSHER, Plaintiffs, v. JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, JOHNSON & JOHNSON, and BTG INTERNATIONAL LIMITED, Defendants.	Civil Action No. 19-12107 (MEF) (ESK) Hon. Michael E. Farbiarz, U.S.D.J. **DEFENDANTS' RESPONSES & OBJECTIONS TO RELATOR'S NOTICE OF 30(b)(6) DEPOSITION OF JOHNSON & JOHNSON**

Pursuant to Federal Rules of Civil Procedure 26 and 30, Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson (collectively, "J&J"), by its counsel, hereby respond and object to Relator's Amended Notice of 30(b)(6) Deposition of Johnson & Johnson, dated February 7, 2024 ("Deposition Notice").

GENERAL OBJECTIONS

The following General Objections are generally applicable to each of the Topics. These General Objections are made herein, rather than repeated throughout, to simplify J&J's responses,

and have the same force and effect as if set forth fully in response to each individual Topic. A failure to repeat any portion of these General Objections in any particular response does not constitute a waiver or relinquishment of that objection by J&J.

1. Defendants object to the March 6, 2024 date in the Deposition Notice as unduly burdensome. Defendants will work with Relator to arrive at a mutually agreeable date, time, and location for such a deposition.

2. Defendants object to the Deposition Notice, the Definitions, and each Topic to the extent they impose upon J&J discovery obligations different from, or in addition to, the Federal Rules of Civil Procedure, the Local Civil Rules of the United States District Court for the District of New Jersey, any applicable court order or directive, and/or any stipulation or agreement of the parties.

3. J&J objects to the Deposition Notice to the extent that it fails to comply with either the "reasonable particularity" or "reasonably available to the organization" requirements set forth in Federal Rule of Civil Procedure 30(b)(6).

4. J&J objects to each Topic to the extent that it seeks information that is not within J&J's possession, custody, or control, and can be located following a reasonable search.

5. J&J objects to each Topic to the extent that it seeks discovery that is overly broad, unduly burdensome, not relevant to any claim or defense in this action, and is disproportionate to the needs of the case. For example, J&J objects to each Topic to the extent that it seeks *all* "facts," "issues," or "materials" concerning a particular subject matter.

6. J&J objects to each Topic to the extent that it is duplicative of other discovery taken in this case or seeks discovery that is more easily available through other, less burdensome means.

7. J&J objects to the Deposition Notice and each Topic to the extent they seek

information protected from disclosure by the attorney-client privilege, work product privilege, and/or other any other applicable privilege or protection. The inadvertent disclosure of any such information shall not constitute a waiver of any applicable privilege or immunity.

8. Defendants object to the Deposition Notice to the extent that it seeks information about matters as to which J&J's employees do not have factual knowledge. By stating that it will produce a witness to testify in response to a Topic, J&J does not admit or represent that it has any relevant knowledge or information on that Topic, but instead merely that the designated witness will testify subject to J&J's objections to the extent that non-privileged, relevant knowledge or information on the Topic is reasonably available to J&J and can be located after a reasonable search.

9. J&J objects to each Topic to the extent that it seeks information covered by a confidentiality agreement with a third party.

10. J&J objects to each Topic to the extent that it seeks information protected from disclosure by the constitutional and/or statutory privacy rights of third persons, including HIPAA.

11. J&J objects to each Topic to the extent that it seeks to obtain expert testimony from a lay person or fact witness, or to prematurely obtain expert testimony.

12. Defendants object to each Topic to the extent that it is unlimited in temporal or geographic scope.

13. Defendants object to each Topic to the extent any responsive information has been produced by Relator with designation under Stipulated Amended Discovery Confidentiality Order ("Protective Order") (Dkt. 175), thus precluding Defendants' personnel from reviewing and testifying as to such information.

14. Defendants General and Specific Objections set forth herein are made without

waiver of their right to object on any additional grounds to any of the Topics prior to or during the deposition of any witness taken in response to the Deposition Notice. Further, Defendants' designation of a witness to testify in response to the Deposition Notice is made without waiver of any objections, including as to relevancy, materiality, privilege, or admissibility of any information in this or any subsequent proceeding or at the trial of this or any other action.

OBJECTIONS TO RELATOR'S DEFINITIONS AND INSTRUCTIONS

1. J&J objects to Relator's definition of "Janssen" to as overbroad, unduly burdensome, oppressive, vague and ambiguous, and seeking discovery not relevant to any claim or defense in this action and disproportionate to the needs of the case. Relator's definition of "Janssen" includes entities or persons outside of Janssen's possession, custody, or control, and calls for information that may be subject to confidentiality agreements and/or protected by the attorney-client privilege, work product privilege, or other any other applicable privilege or immunity. J&J is responding on its behalf only and will interpret "Janssen" to refer only to the parties in this action, Janssen Biotech, Inc., Janssen Oncology Inc., Janssen Research & Development, LLC, and Johnson & Johnson.

2. J&J objects to the definition of "Commercial Success Argument" vague, overbroad, unduly burdensome, seeking discovery not relevant to any claim or defense and disproportionate to the needs of the case to the extent it extends to any administrative proceeding or litigation concerning the validity of the '438 Patent. J&J will construe "Commercial Success Argument" to refer to the commercial success argument made to the USPTO during the prosecution of the '340 Application only.

3. Defendants object to the definition of "Zytiga" as vague, overbroad, unduly burdensome, seeking discovery not relevant to any claim or defense and disproportionate to the

needs of the case to the extent it is intended to cover anything other than the abiraterone acetate product and FDA approved uses that are the subject of NDA 202379, and to the extent it is intended to cover any products sold outside the United States.

4. Defendants object insofar as the term "Person" is not used in the Topics.

5. Defendants objects to Relator's Instructions to the extent that they attempt to impose obligations on Defendants different from or in addition to those required by the Stipulated Amended Discovery Confidentiality Order ("Protective Order") (Dkt. 175). In designating witnesses to testify in response to the Deposition Notice, J&J will comply with the Protective Order. Any disclosures made in the context of the Deposition(s) are subject to the Protective Order or any amended versions of such order subsequently entered by the Court.

6. Defendants object to each Topic and Definition to the extent that it contains undefined terms that are subject to multiple interpretations, thus rendering the subject matter vague and ambiguous. To the extent J&J designates witnesses to testify in response to the Deposition Notice, those witnesses will testify based upon J&J's interpretation of undefined terms and understanding of certain terms set forth herein, which may differ from Relators' interpretations.

RESPONSES AND OBJECTIONS TO RELATOR'S TOPICS

TOPIC NO. 1: Defendants' prosecution of all applications leading to the '438 Patent, including the '340 and '440 Applications.

RESPONSE TO TOPIC NO. 1: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "all applications" and "leading to."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation, and calls for information pre-dating J&J's acquisition of Cougar Biotechnology, Inc. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding J&J's prosecution of the '440 Application following its acquisition of Cougar Biotechnology, Inc., and J&J's prosecution of the '340 Application to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 2: Defendants' due diligence relating to the Commercial Success Argument prior to submitting that argument to the Patent Office.

RESPONSE TO TOPIC NO. 2: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the

needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined term "due diligence."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J further objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protections. J&J also objects to this Topic to the extent it is cumulative to, or duplicative of, other discovery or information that has already been provided to Relator.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the commercial success argument presented to the USPTO during the prosecution of the '340 Application to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 3: All facts, issues, and materials that Defendants relied upon or considered in making the Commercial Success Argument.

RESPONSE TO TOPIC NO. 3: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "all," "issues," "materials," "relied upon" and "considered."

J&J further objects to this Topic as overbroad, unduly burdensome, not relevant to any

claim or defense and disproportionate to the needs of this litigation to the extent that it contains no temporal or date limitation. J&J objects to this Topic to the extent it calls for information, documents, or things generated on or after September 2, 2014—the date the '438 Patent issued. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control. J&J also objects to this Topic to the extent it is cumulative to, or duplicative of, other discovery or information that has already been provided to Relator.

J&J further objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, the work-product privilege, and/or any other applicable privilege or immunity.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the commercial success argument presented to the USPTO in connection with the '340 Application to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 4: Defendants' operating procedures, code of ethics, standards, internal guidance, and requirements for any directors, executives, employees, agents, inventors, and patent prosecuting attorneys when prosecuting patent applications.

RESPONSE TO TOPIC NO. 4: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "operating procedures," "standards," "internal guidance" and "requirements."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate

to the needs of this case to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated on or after September 2, 2014—the date the '438 Patent issued.

J&J also objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, the work-product privilege, and/or any other applicable privilege or immunity.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding J&J's policies and procedures applicable to its in-house patent attorneys, and relating to those attorneys' patent prosecution duties, that were in place between July 9, 2009 and December 31, 2014, to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 5: The hierarchy, structure, and responsibilities of the relevant legal and patent prosecution departments for Defendants.

RESPONSE TO TOPIC NO. 5: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "hierarchy," "structure," and "responsibilities."

J&J further objects to this Topic as overbroad, overly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated on or after September 2, 2014—the date the '438 Patent issued.

J&J also objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, the work-product privilege, and/or any other applicable privilege or immunity.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the structure, organization, and responsibilities of the J&J law department's patent prosecution group during the period between July 9, 2009 and December 31, 2014 to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 6: Defendants' sales of Zytiga from 2011 to the present time, including, without limitation, which Defendant entities were involved in making the sale, and transactional details such as the number of units sold, the price per unit, the purchaser, and total sales by date.

RESPONSE TO TOPIC NO. 6: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "sales," "transactional details," "purchaser," and the phrase "without limitation."

J&J further objects to this Topic as overbroad, overly burdensome, and disproportionate to the needs of this case to the extent calls for information, documents, or things generated prior to September 2, 2014—the date the '438 Patent issued.

J&J further objects to the disclosure of commercial, financial, transactional, and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case. J&J also objects to this Topic as

overbroad, unduly burdensome, disproportionate to the needs of this case to the extent it seeks information regarding sales of Zytiga that were not paid for, or reimbursed by, any of the government entities named in the Second Amended Complaint; sales that were not paid for by such government entities have no relevance to any disputed matter of law or fact in this case.

J&J further objects to this Topic to the extent it is cumulative to, or duplicative of, other discovery or information that has already been provided to Relator. J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the sales and pricing data previously produced to Relator in response to Relator's Requests for Production 32, 35, and 36. *See* ZYTIGA_LIT_05587250 - ZYTIGA_LIT_05587253; ZYTIGA_LIT_05597118 - ZYTIGA_LIT_05597123.

TOPIC NO. 7: Defendants' sales of Zytiga from 2011 to the present time to Medicare Plan D sponsors, the Department of Veterans Affairs, Medicaid programs, and Zytiga Specialty Pharmacies for units intended for Government purchase or payment, including, without limitation, which Defendant entities were involved in making the sale, and transactional detail of the number of units sold, the price per unit, the purchaser, and total sales by date.

RESPONSE TO TOPIC NO. 7: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "sales," "Medicaid programs," "intended," "transactional detail," "purchaser," and the phrase "without limitation."

J&J further objects to this Topic as overbroad, overly burdensome, and disproportionate to the needs of this case to the extent calls for information, documents, or things generated prior to September 2, 2014—the date the '438 Patent issued.

J&J also objects to this Topic to the extent that it seeks information that is not within J&J's

possession, custody, or control, or information that is already in Relator's possession, custody, or control. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Relator's Requests for Production No. 32, 35, and 36.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the sales and pricing data previously produced to Relator in response to Relator's Requests for Production 32, 35, and 36. *See* ZYTIGA_LIT_05587250 - ZYTIGA_LIT_05587253; ZYTIGA_LIT_05597118 - ZYTIGA_LIT_05597123.

TOPIC NO. 8: Defendants' prices, including rebates or similar reimbursements, for Zytiga to any government purchaser or payor for Zytiga from 2011 to the present time, including, without limitation, the setting of prices, and the calculation of rebates or similar reimbursements.

RESPONSE TO TOPIC NO. 8: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "rebates," "similar reimbursements," "government purchaser or payor," and "setting of prices."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent calls for information, documents, or things generated prior to September 2, 2014—the date the '438 Patent issued.

J&J objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control, or information that is already in Relator's possession, custody, or

control. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Relator's Requests for Production Nos. 32, 35, and 36.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the sales and pricing data previously produced to Relator in response to Relator's Requests for Production 32, 35, and 36. *See* ZYTIGA_LIT_05587250 - ZYTIGA_LIT_05587253; ZYTIGA_LIT_05597118 - ZYTIGA_LIT_05597123.

TOPIC NO. 9: Defendants' agreements with Medicare Plan D sponsors, the Department of Veterans Affairs, and the Department of Health & Human Services (including the Centers for Medicare & Medicaid Services) for Zytiga from 2011 to the present time.

RESPONSE TO TOPIC NO. 9: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined term "agreements."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent calls for information, documents, or things generated prior to September 2, 2014—the date the '438 Patent issued.

J&J objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control, or information that is already in Relator's possession, custody, or control. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Relator's Request for Production No. 31.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the terms of the final, written contracts and/or written amendments between J&J and government-funded health plans or programs, or other governmental entity purchases that were previously produced in response to Relator's Requests for Production. *See* ZYTIGA_LIT_05415095 - ZYTIGA_LIT_05418027.

TOPIC NO. 10: The listing of Zytiga in the Federal Supply Schedule.

RESPONSE TO TOPIC NO. 10: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined term "listing."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated prior to September 2, 2014—the date the '438 Patent issued. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J further objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the listing of Zytiga in the Federal Supply Schedule following the issuance of the '438 Patent to the extent that

responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 11: The listing of the '438 Patent in the Orange Book (the U.S. Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations), and the subsequent institution of patent litigation against generic competitors.

RESPONSE TO TOPIC NO. 11: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined term "listing."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation.

J&J further objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J also objects to this Topic to the extent it is cumulative to, or duplicative of, other discovery or information that has already been provided to Relator.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it calls for information, documents, or things regarding "the subsequent institution of patent litigation against generic competitors." Such information has no relevance to any disputed matter of law or fact in this case, at least in part because the Court previously rejected the claim that the underlying patent infringement litigation was a "sham."

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the decision to list, or continue to list, the '438 Patent in the FDA's Orange Book to the extent that responsive, non-

privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 12: The roles, Rights, and responsibilities of each corporate entity that is a direct or indirect subsidiary of Johnson & Johnson, including Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, that participated in the research, development, manufacture, marketing, or sale of Zytiga.

RESPONSE TO TOPIC NO. 12: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "roles," "responsibilities," "indirect subsidiary," and "development."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation. J&J further objects to the disclosure of commercial and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

J&J will not produce a witness in response to this Topic, which is too vague, ambiguous, broad, ill-defined, and burdensome to properly prepare a witness.

TOPIC NO. 13: The role, Rights, and responsibilities of Johnson & Johnson relating to the '340 Application, the '440 Application, the '213 Patent, and the '438 Patent.

RESPONSE TO TOPIC NO. 13: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "roles," and "responsibilities."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, in particular in response to Topics 1, 2, and 3.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

J&J will not produce a witness in response to this Topic, which is too vague, ambiguous, broad, ill-defined, and burdensome to properly prepare a witness. To the extent this Topic is relevant to Relator's claims, it is duplicative of other Topics for which J&J has produced a witness, including Topics 1, 2, and 3.

TOPIC NO. 14: The acquisition, license, or transfer of any Rights related to the '213 Patent.

RESPONSE TO TOPIC NO. 14: J&J objects to this Topic as overly broad, unduly burdensome, indefinite, vague and ambiguous, seeking information that is neither relevant to a claim or defense in this action nor proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined

terms "acquisition," "license," and "transfer."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control, or information that is already in Relator's possession, custody, or control. J&J also objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Relator's Request for Production No. 53.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J also objects to this Topic to the extent it seeks information subject to the right of third parties, including obligations of confidentiality between J&J and a third party.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify regarding the license agreement between J&J and BTG concerning the '213 Patent to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 15: The acquisition, license, or transfer of any Rights related to the '438 Patent.

RESPONSE TO TOPIC NO. 15: J&J objects to this Topic as overly broad, unduly burdensome, indefinite, vague and ambiguous, seeking information that is neither relevant to a claim or defense in this action nor proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "acquisition," "license," and "transfer."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control, or information that is already in Relator's possession, custody, or control. J&J also objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Relator's Request for Production No. 53.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J also objects to this Topic to the extent it seeks information subject to the right of third parties, including obligations of confidentiality between J&J and a third party.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case.

J&J will not produce a witness in response to this Topic, which is irrelevant to Relator's claims and too vague, ambiguous, broad, ill-defined, irrelevant and burdensome to properly prepare a witness.

TOPIC NO. 16: Any actions taken by Johnson & Johnson to enforce the '438 Patent, and any benefits derived by Johnson & Johnson from enforcement of the '438 patent.

RESPONSE TO TOPIC NO. 16: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the terms "action," "enforce," "benefits," and "enforcement."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, in particular in response to Topic 11.

J&J further objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

J&J objects to this Topic as unduly burdensome on the ground that it seeks information regarding highly confidential commercial documents and/or communications with no relevance to any disputed matter of law or fact in this case, at least in part because the Court previously rejected any claim that the underlying patent infringement litigation was a "sham."

J&J will not provide a witness for this topic because this Topic is irrelevant to Relator's claims and too broad, burdensome, and ill-defined to properly prepare a witness.

TOPIC NO. 17: Any actions taken by Johnson & Johnson related to the '340 Application and the '440 Application.

RESPONSE TO TOPIC NO. 17: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination,

for example, in its use of the undefined term "actions."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation, and calls for information pre-dating J&J's acquisition of Cougar Biotechnology, Inc. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control. J&J also objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, in particular in response to Topic 1, 2, and 3.

J&J further objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection .

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information on highly confidential commercial documents and/or communications with no relevance to any disputed matter of law or fact in this case, at least in part because the Court previously ruled against any claim that the underlying patent infringement litigation was a "sham."

J&J will not provide a witness for this topic because this Topic is irrelevant to Relator's claims and too broad, burdensome, and ill-defined to properly prepare a witness. To this extent this Topic is relevant to Relator's claims it is duplicative of Topics for which J&J has provided a witness, including Topics 1, 2, and 3.

TOPIC NO. 18: The sale of any Authorized Generic of Zytiga, including, without limitation, any contracts or licenses granting Patriot Pharmaceuticals the right to sell an Authorized Generic; the ownership and control of Patriot Pharmaceuticals; and Johnson & Johnson's goals, expectations, and strategy with respect to the sale of Authorized Generics.

RESPONSE TO TOPIC NO. 18: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "sale," "contracts," "licenses," "right," "sell," "ownership," "control," "goals," "expectations," and "strategy."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J further objects to the disclosure of commercial, financial, transactional, and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, disproportionate to the needs of this case, and not relevant to any disputed issue of law or fact.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J also objects to this Topic to the extent it seeks information subject to the right of third parties, including obligations of confidentiality between J&J and a third party.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to

the needs of this case to the extent it calls for information, documents, or things regarding "contracts or licenses granting Patriot Pharmaceuticals the right to sell an Authorized Generic; the ownership and control of Patriot Pharmaceuticals; and Johnson & Johnson's goals, expectations, and strategy with respect to the sale of Authorized Generics." Such information has no relevance to any disputed matter of law or fact in this case.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the actual sales of Authorized Generics by Patriot Pharmaceuticals between November 23, 2018 and December 31, 2020 to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 19: Johnson & Johnson's expectations, goals, and strategy with respect to launching a coated version of Zytiga.

RESPONSE TO TOPIC NO. 19: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "expectations," "goals," and "strategy."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case.

J&J will not produce a witness in response to this Topic because it is irrelevant to Relator's claims and too vague, ambiguous, broad, ill-defined, and burdensome to properly prepare a witness.

TOPIC NO. 20: Johnson & Johnson's expectations, goals, and strategy with respect to launching a 500 mg version of Zytiga.

RESPONSE TO TOPIC NO. 20: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "expectations," "goals," and "strategy."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation.. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case.

J&J will not produce a witness in response to this Topic because it is irrelevant to Relator's

claims and too vague, ambiguous, broad, ill-defined, and burdensome to properly prepare a witness.

TOPIC NO. 21: Any actual or proposed initiatives, studies, or programs to mitigate prednisone coadministration, including, without limitation, the funding or conduct of studies, trials, or other initiatives to explore a reduction in the required dosage for prednisone coadministration, or the substitution of prednisone with another chemical substance when co-administering with Zytiga.

RESPONSE TO TOPIC NO. 21: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "initiatives," "studies," "programs," "mitigate," "funding," "trials," "reduction," "required dosage," "substitution," and "chemical substance."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated for information before J&J's acquisition of Cougar Biotechnology, Inc or after September 2, 2014—the date the '438 Patent issued. J&J also objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J objects to this Topic to the extent it seeks information subject to the rights of third parties, including obligations of confidentiality between any J&J and a third party.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding any studies between July 9, 2009, and September 2, 2014, regarding the administration of abiraterone acetate without

prednisone for the treatment of prostate cancer, to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 22: Any efforts to encourage or persuade prescribers, purchases, and the market to accept prednisone coadministration when prescribing Zytiga.

RESPONSE TO TOPIC NO. 22: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "efforts," "encourage," "persuade," "prescribers," "purchasers," "the market," "accept," and "prescribing."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated for information before J&J's acquisition of Cougar Biotechnology, Inc or after September 2, 2014—the date the '438 Patent issued. J&J also objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control.

J&J also objects to the disclosure of commercial, marketing, advertising, regulatory, and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J objects to this Topic to the extent it seeks information subject to the rights of third parties, including obligations of confidentiality between any J&J and a third party.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal

conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding J&J's methods of marketing and promoting Zytiga in the United States between July 9, 2009 and September 2, 2014 to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 23: Johnson & Johnson's knowledge concerning the strengths, weaknesses, threats, and opportunities relating to Zytiga compared with actual or potential competitors, including, without limitation, any strategic analysis of Zytiga's competitive position, advantages, and disadvantages against competing treatments.

RESPONSE TO TOPIC NO. 23: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "knowledge," "strengths," "weaknesses," "threats," "opportunities," "actual or potential competitors," "strategic analysis," "competitive position," "advantages," "disadvantages," and "competing treatments."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated for information before J&J's acquisition of Cougar Biotechnology, Inc or after September 2, 2014—the date the '438 Patent issued. J&J also objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control.

J&J further objects to the disclosure of commercial, marketing, advertising, regulatory, and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J objects to this Topic to the extent it seeks information subject to the rights of third parties, including obligations of confidentiality between any J&J and a third party.

J&J also object to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding J&J's methods of marketing and promoting Zytiga in the United States between July 9, 2009 and September 2, 2014, and generally regarding business plans concerning Zytiga between July 9, 2009, and September 2, 2014, to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 24: Johnson & Johnson's market share or generic erosion analysis of Zytiga's actual or anticipated market share and sales considering any loss of exclusivity caused by the expiration of regulatory or patent exclusivities.

RESPONSE TO TOPIC NO. 24: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "generic erosion analysis," "sales," "expiration," and "exclusivities."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated for information before J&J's acquisition of Cougar Biotechnology, Inc. or after September 2, 2014—the date the '438 Patent issued. J&J also objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control. J&J also objects to this Topic

to the extent it is cumulative to, or duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Discovery Requests Nos. 22 and 25.

J&J further objects to the disclosure of commercial, marketing, advertising, regulatory, and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J objects to this Topic to the extent it seeks information subject to the rights of third parties, including obligations of confidentiality between any J&J and a third party.

J&J also object to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the anticipated timing of market entry of Generic Zytiga and the impact of that entry on Zytiga's sales and market share to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 25: The negotiation and terms of any settlement with generic competitors sued for patent infringement relating to Zytiga.

RESPONSE TO TOPIC NO. 25: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "negotiation," "terms," and "settlement."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate

to the needs of this case to the extent it contains no temporal or date limitation.

J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Relator's Request for Production No. 51.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J further objects to this Topic to the extent it seeks information subject to the rights of third parties, including obligations of confidentiality between J&J and any third party.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because the Topic has no relevance to any disputed matter of law or fact in this case.

J&J will not produce a witness in response to this Topic.

TOPIC NO. 26: The negotiation and terms of any exclusive pharmacy agreements that was intended to, or had the effect of, maintaining or protecting Zytiga's market share against generic competition.

RESPONSE TO TOPIC NO. 26: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "negotiation," "exclusive pharmacy agreements," and "protecting."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or

control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J further objects to this Topic to the extent it seeks information subject to the rights of third parties, including obligations of confidentiality between J&J and any third party.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because the Topic has no relevance to any disputed matter of law or fact in this case.

J&J will not produce a witness in response to this Topic.

Dated: March 2, 2024

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA; STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA, *ex rel*. ZACHARY SILBERSHER, Plaintiffs, v. JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, JOHNSON & JOHNSON, and BTG INTERNATIONAL LIMITED, Defendants.	Civil Action No. 19-12107 (MEF) (ESK) Hon. Michael E. Farbiarz, U.S.D.J. **DEFENDANTS' RESPONSES & OBJECTIONS TO RELATOR'S NOTICE OF 30(b)(6) DEPOSITION OF JANSSEN BIOTECH, INC.**

Pursuant to Federal Rules of Civil Procedure 26 and 30, Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson (collectively, "J&J"), by its counsel, hereby respond and object to Relator's Amended Notice of 30(b)(6) Deposition of Janssen Biotech, Inc., dated February 7, 2024 ("Deposition Notice").

GENERAL OBJECTIONS

The following General Objections are generally applicable to each of the Topics. These General Objections are made herein, rather than repeated throughout, to simplify J&J's responses,

and have the same force and effect as if set forth fully in response to each individual Topic. A failure to repeat any portion of these General Objections in any particular response does not constitute a waiver or relinquishment of that objection by J&J.

1. Defendants object to the March 6, 2024 date in the Deposition Notice as unduly burdensome. Defendants will work with Relator to arrive at a mutually agreeable date, time, and location for such a deposition.

2. Defendants object to the Deposition Notice, the Definitions, and each Topic to the extent they impose upon J&J discovery obligations different from, or in addition to, the Federal Rules of Civil Procedure, the Local Civil Rules of the United States District Court for the District of New Jersey, any applicable court order or directive, and/or any stipulation or agreement of the parties.

3. J&J objects to the Deposition Notice to the extent that it fails to comply with either the "reasonable particularity" or "reasonably available to the organization" requirements set forth in Federal Rule of Civil Procedure 30(b)(6).

4. J&J objects to each Topic to the extent that it seeks information that is not within J&J's possession, custody, or control, and can be located following a reasonable search.

5. J&J objects to each Topic to the extent that it seeks discovery that is overly broad, unduly burdensome, not relevant to any claim or defense in this action, and is disproportionate to the needs of the case. For example, J&J objects to each Topic to the extent that it seeks *all* "facts," "issues," or "materials" concerning a particular subject matter.

6. J&J objects to each Topic to the extent that it is duplicative of other discovery taken in this case or seeks discovery that is more easily available through other, less burdensome means.

7. J&J objects to the Deposition Notice and each Topic to the extent they seek

information protected from disclosure by the attorney-client privilege, work product privilege, and/or other any other applicable privilege or protection. The inadvertent disclosure of any such information shall not constitute a waiver of any applicable privilege or immunity.

8. Defendants object to the Deposition Notice to the extent that it seeks information about matters as to which J&J's employees do not have factual knowledge. By stating that it will produce a witness to testify in response to a Topic, J&J does not admit or represent that it has any relevant knowledge or information on that Topic, but instead merely that the designated witness will testify subject to J&J's objections to the extent that non-privileged, relevant knowledge or information on the Topic is reasonably available to J&J and can be located after a reasonable search.

9. J&J objects to each Topic to the extent that it seeks information covered by a confidentiality agreement with a third party.

10. J&J objects to each Topic to the extent that it seeks information protected from disclosure by the constitutional and/or statutory privacy rights of third persons, including HIPAA.

11. J&J objects to each Topic to the extent that it seeks to obtain expert testimony from a lay person or fact witness, or to prematurely obtain expert testimony.

12. Defendants object to each Topic to the extent that it is unlimited in temporal or geographic scope.

13. Defendants object to each Topic to the extent any responsive information has been produced by Relator with designation under Stipulated Amended Discovery Confidentiality Order ("Protective Order") (Dkt. 175), thus precluding Defendants' personnel from reviewing and testifying as to such information.

14. Defendants General and Specific Objections set forth herein are made without

waiver of their right to object on any additional grounds to any of the Topics prior to or during the deposition of any witness taken in response to the Deposition Notice. Further, Defendants' designation of a witness to testify in response to the Deposition Notice is made without waiver of any objections, including as to relevancy, materiality, privilege, or admissibility of any information in this or any subsequent proceeding or at the trial of this or any other action.

OBJECTIONS TO RELATOR'S DEFINITIONS AND INSTRUCTIONS

1. J&J objects to Relator's definition of "Janssen" to as overbroad, unduly burdensome, oppressive, vague and ambiguous, and seeking discovery not relevant to any claim or defense in this action and disproportionate to the needs of the case. Relator's definition of "Janssen" includes entities or persons outside of Janssen's possession, custody, or control, and calls for information that may be subject to confidentiality agreements and/or protected by the attorney-client privilege, work product privilege, or other any other applicable privilege or immunity. J&J is responding on its behalf only and will interpret "Janssen" to refer only to the parties in this action, Janssen Biotech, Inc., Janssen Oncology Inc., Janssen Research & Development, LLC, and Johnson & Johnson.

2. J&J objects to the definition of "Commercial Success Argument" vague, overbroad, unduly burdensome, seeking discovery not relevant to any claim or defense and disproportionate to the needs of the case to the extent it extends to any administrative proceeding or litigation concerning the validity of the '438 Patent. J&J will construe "Commercial Success Argument" to refer to the commercial success argument made to the USPTO during the prosecution of the '340 Application only.

3. Defendants object to the definition of "Zytiga" as vague, overbroad, unduly burdensome, seeking discovery not relevant to any claim or defense and disproportionate to the

needs of the case to the extent it is intended to cover anything other than the abiraterone acetate product and FDA approved uses that are the subject of NDA 202379, and to the extent it is intended to cover any products sold outside the United States.

4. Defendants object insofar as the term "Person" is not used in the Topics.

5. Defendants objects to Relator's Instructions to the extent that they attempt to impose obligations on Defendants different from or in addition to those required by the Stipulated Amended Discovery Confidentiality Order ("Protective Order") (Dkt. 175). In designating witnesses to testify in response to the Deposition Notice, J&J will comply with the Protective Order. Any disclosures made in the context of the Deposition(s) are subject to the Protective Order or any amended versions of such order subsequently entered by the Court.

6. Defendants object to each Topic and Definition to the extent that it contains undefined terms that are subject to multiple interpretations, thus rendering the subject matter vague and ambiguous. To the extent J&J designates witnesses to testify in response to the Deposition Notice, those witnesses will testify based upon J&J's interpretation of undefined terms and understanding of certain terms set forth herein, which may differ from Relators' interpretations.

RESPONSES AND OBJECTIONS TO RELATOR'S TOPICS

TOPIC NO. 1: Defendants' prosecution of all applications leading to the '438 Patent, including the '340 and '440 Applications.

RESPONSE TO TOPIC NO. 1: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "all applications" and "leading to."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation, and calls for information pre-dating J&J's acquisition of Cougar Biotechnology, Inc. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding J&J's prosecution of the '440 Application following its acquisition of Cougar Biotechnology, Inc., and J&J's prosecution of the '340 Application to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 2: Defendants' due diligence relating to the Commercial Success Argument prior to submitting that argument to the Patent Office.

RESPONSE TO TOPIC NO. 2: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the

needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined term "due diligence."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J further objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protections. J&J also objects to this Topic to the extent it is cumulative to, or duplicative of, other discovery or information that has already been provided to Relator.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the commercial success argument presented to the USPTO during the prosecution of the '340 Application to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 3: All facts, issues, and materials that Defendants relied upon or considered in making the Commercial Success Argument.

RESPONSE TO TOPIC NO. 3: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "all," "issues," "materials," "relied upon" and "considered."

J&J further objects to this Topic as overbroad, unduly burdensome, not relevant to any

claim or defense and disproportionate to the needs of this litigation to the extent that it contains no temporal or date limitation. J&J objects to this Topic to the extent it calls for information, documents, or things generated on or after September 2, 2014—the date the '438 Patent issued. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control. J&J also objects to this Topic to the extent it is cumulative to, or duplicative of, other discovery or information that has already been provided to Relator.

J&J further objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, the work-product privilege, and/or any other applicable privilege or immunity.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the commercial success argument presented to the USPTO in connection with the '340 Application to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 4: Defendants' operating procedures, code of ethics, standards, internal guidance, and requirements for any directors, executives, employees, agents, inventors, and patent prosecuting attorneys when prosecuting patent applications.

RESPONSE TO TOPIC NO. 4: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "operating procedures," "standards," "internal guidance" and "requirements."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate

to the needs of this case to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated on or after September 2, 2014—the date the '438 Patent issued.

J&J also objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, the work-product privilege, and/or any other applicable privilege or immunity.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding J&J's policies and procedures applicable to its in-house patent attorneys, and relating to those attorneys' patent prosecution duties, that were in place between July 9, 2009 and December 31, 2014, to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 5: The hierarchy, structure, and responsibilities of the relevant legal and patent prosecution departments for Defendants.

RESPONSE TO TOPIC NO. 5: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "hierarchy," "structure," and "responsibilities."

J&J further objects to this Topic as overbroad, overly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated on or after September 2, 2014—the date the '438 Patent issued.

J&J also objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, the work-product privilege, and/or any other applicable privilege or immunity.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the structure, organization, and responsibilities of the J&J law department's patent prosecution group during the period between July 9, 2009 and December 31, 2014 to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 6: Defendants' sales of Zytiga from 2011 to the present time, including, without limitation, which Defendant entities were involved in making the sale, and transactional details such as the number of units sold, the price per unit, the purchaser, and total sales by date.

RESPONSE TO TOPIC NO. 6: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "sales," "transactional details," "purchaser," and the phrase "without limitation."

J&J further objects to this Topic as overbroad, overly burdensome, and disproportionate to the needs of this case to the extent calls for information, documents, or things generated prior to September 2, 2014—the date the '438 Patent issued.

J&J further objects to the disclosure of commercial, financial, transactional, and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case. J&J also objects to this Topic as

overbroad, unduly burdensome, disproportionate to the needs of this case to the extent it seeks information regarding sales of Zytiga that were not paid for, or reimbursed by, any of the government entities named in the Second Amended Complaint; sales that were not paid for by such government entities have no relevance to any disputed matter of law or fact in this case.

J&J further objects to this Topic to the extent it is cumulative to, or duplicative of, other discovery or information that has already been provided to Relator. J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the sales and pricing data previously produced to Relator in response to Relator's Requests for Production 32, 35, and 36. *See* ZYTIGA_LIT_05587250 - ZYTIGA_LIT_05587253; ZYTIGA_LIT_05597118 - ZYTIGA_LIT_05597123.

TOPIC NO. 7: Defendants' sales of Zytiga from 2011 to the present time to Medicare Plan D sponsors, the Department of Veterans Affairs, Medicaid programs, and Zytiga Specialty Pharmacies for units intended for Government purchase or payment, including, without limitation, which Defendant entities were involved in making the sale, and transactional detail of the number of units sold, the price per unit, the purchaser, and total sales by date.

RESPONSE TO TOPIC NO. 7: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "sales," "Medicaid programs," "intended," "transactional detail," "purchaser," and the phrase "without limitation."

J&J further objects to this Topic as overbroad, overly burdensome, and disproportionate to the needs of this case to the extent calls for information, documents, or things generated prior to September 2, 2014—the date the '438 Patent issued.

J&J also objects to this Topic to the extent that it seeks information that is not within J&J's

possession, custody, or control, or information that is already in Relator's possession, custody, or control. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Relator's Requests for Production No. 32, 35, and 36.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the sales and pricing data previously produced to Relator in response to Relator's Requests for Production 32, 35, and 36. *See* ZYTIGA_LIT_05587250 - ZYTIGA_LIT_05587253; ZYTIGA_LIT_05597118 - ZYTIGA_LIT_05597123.

TOPIC NO. 8: Defendants' prices, including rebates or similar reimbursements, for Zytiga to any government purchaser or payor for Zytiga from 2011 to the present time, including, without limitation, the setting of prices, and the calculation of rebates or similar reimbursements.

RESPONSE TO TOPIC NO. 8: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "rebates," "similar reimbursements," "government purchaser or payor," and "setting of prices."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent calls for information, documents, or things generated prior to September 2, 2014—the date the '438 Patent issued.

J&J objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control, or information that is already in Relator's possession, custody, or

control. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Relator's Requests for Production Nos. 32, 35, and 36.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the sales and pricing data previously produced to Relator in response to Relator's Requests for Production 32, 35, and 36. *See* ZYTIGA_LIT_05587250 - ZYTIGA_LIT_05587253; ZYTIGA_LIT_05597118 - ZYTIGA_LIT_05597123.

TOPIC NO. 9: Defendants' agreements with Medicare Plan D sponsors, the Department of Veterans Affairs, and the Department of Health & Human Services (including the Centers for Medicare & Medicaid Services) for Zytiga from 2011 to the present time.

RESPONSE TO TOPIC NO. 9: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined term "agreements."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent calls for information, documents, or things generated prior to September 2, 2014—the date the '438 Patent issued.

J&J objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control, or information that is already in Relator's possession, custody, or control. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Relator's Request for Production No. 31.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the terms of the final, written contracts and/or written amendments between J&J and government-funded health plans or programs, or other governmental entity purchases that were previously produced in response to Relator's Requests for Production. *See* ZYTIGA_LIT_05415095 - ZYTIGA_LIT_05418027.

TOPIC NO. 10: The listing of Zytiga in the Federal Supply Schedule.

RESPONSE TO TOPIC NO. 10: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined term "listing."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated prior to September 2, 2014—the date the '438 Patent issued. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J further objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the listing of Zytiga in the Federal Supply Schedule following the issuance of the '438 Patent to the extent that

responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 11: The listing of the '438 Patent in the Orange Book (the U.S. Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations), and the subsequent institution of patent litigation against generic competitors.

RESPONSE TO TOPIC NO. 11: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined term "listing."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation.

J&J further objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J also objects to this Topic to the extent it is cumulative to, or duplicative of, other discovery or information that has already been provided to Relator.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it calls for information, documents, or things regarding "the subsequent institution of patent litigation against generic competitors." Such information has no relevance to any disputed matter of law or fact in this case, at least in part because the Court previously rejected the claim that the underlying patent infringement litigation was a "sham."

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the decision to list, or continue to list, the '438 Patent in the FDA's Orange Book to the extent that responsive, non-

privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 12: The roles, Rights, and responsibilities of Janssen Biotech, Inc. in the research, development, manufacture, marketing, or sale of Zytiga.

RESPONSE TO TOPIC NO. 12: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "roles," "responsibilities," and "development."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation. J&J further objects to the disclosure of commercial and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

J&J will not produce a witness in response to this Topic, which is too vague, ambiguous, broad, ill-defined, and burdensome to properly prepare a witness.

TOPIC NO. 13: The role, Rights, and responsibilities of Janssen Biotech, Inc. relating to the '340 Application, the '440 Application, the '213 Patent, and the '438 Patent.

RESPONSE TO TOPIC NO. 13: J&J objects to this Topic as indefinite, vague,

ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "roles," and "responsibilities."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, in particular in response to Topics 1, 2, and 3.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

J&J will not produce a witness in response to this Topic, which is too vague, ambiguous, broad, ill-defined, and burdensome to properly prepare a witness. To the extent this Topic is relevant to Relator's claims, it is duplicative of other Topics for which J&J has produced a witness, including Topics 1, 2, and 3.

TOPIC NO. 14: The acquisition, license, or transfer of any Rights related to the '213 Patent.

RESPONSE TO TOPIC NO. 14: J&J objects to this Topic as overly broad, unduly burdensome, indefinite, vague and ambiguous, seeking information that is neither relevant to a claim or defense in this action nor proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "acquisition," "license," and "transfer."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent that it seeks

information that is not within J&J's possession, custody, or control, or information that is already in Relator's possession, custody, or control. J&J also objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Relator's Request for Production No. 53.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J also objects to this Topic to the extent it seeks information subject to the right of third parties, including obligations of confidentiality between J&J and a third party.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify regarding the license agreement between J&J and BTG concerning the '213 Patent to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 15: The acquisition, license, or transfer of any Rights related to the '438 Patent.

RESPONSE TO TOPIC NO. 15: J&J objects to this Topic as overly broad, unduly burdensome, indefinite, vague and ambiguous, seeking information that is neither relevant to a claim or defense in this action nor proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "acquisition," "license," and "transfer."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control, or information that is already

in Relator's possession, custody, or control. J&J also objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Relator's Request for Production No. 53.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J also objects to this Topic to the extent it seeks information subject to the right of third parties, including obligations of confidentiality between J&J and a third party.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case.

J&J will not produce a witness in response to this Topic, which is irrelevant to Relator's claims and too vague, ambiguous, broad, ill-defined, irrelevant and burdensome to properly prepare a witness.

TOPIC NO. 16: Any actions taken by Janssen Biotech, Inc. to enforce the '438 Patent, and any benefits derived by Janssen Biotech, Inc. from enforcement of the '438 patent.

RESPONSE TO TOPIC NO. 16: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the terms "action," "enforce," "benefits," and "enforcement."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or

control, information that is publicly available, or information that is already in Relator's possession, custody, or control. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, in particular in response to Topic 11.

J&J further objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

J&J objects to this Topic as unduly burdensome on the ground that it seeks information regarding highly confidential commercial documents and/or communications with no relevance to any disputed matter of law or fact in this case, at least in part because the Court previously rejected any claim that the underlying patent infringement litigation was a "sham."

J&J will not provide a witness for this topic because this Topic is irrelevant to Relator's claims and too broad, burdensome, and ill-defined to properly prepare a witness.

TOPIC NO. 17: Any actions taken by Janssen Biotech, Inc. related to the '340 Application and the '440 Application.

RESPONSE TO TOPIC NO. 17: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined term "actions."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation, and calls for information pre-dating J&J's acquisition of Cougar Biotechnology, Inc. J&J further objects to this

Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control. J&J also objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, in particular in response to Topic 1, 2, and 3.

J&J further objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection .

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information on highly confidential commercial documents and/or communications with no relevance to any disputed matter of law or fact in this case, at least in part because the Court previously ruled against any claim that the underlying patent infringement litigation was a "sham."

J&J will not provide a witness for this topic because this Topic is irrelevant to Relator's claims and too broad, burdensome, and ill-defined to properly prepare a witness. To this extent this Topic is relevant to Relator's claims it is duplicative of Topics for which J&J has provided a witness, including Topics 1, 2, and 3.

TOPIC NO. 18: The sale of any Authorized Generic of Zytiga, including, without limitation, any contracts or licenses granting Patriot Pharmaceuticals the right to sell an Authorized Generic; the ownership and control of Patriot Pharmaceuticals; and Janssen Biotech, Inc.'s goals, expectations, and strategy with respect to the sale of Authorized Generics.

RESPONSE TO TOPIC NO. 18: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "sale," "contracts," "licenses," "right," "sell,"

"ownership," "control," "goals," "expectations," and "strategy."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J further objects to the disclosure of commercial, financial, transactional, and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, disproportionate to the needs of this case, and not relevant to any disputed issue of law or fact.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J also objects to this Topic to the extent it seeks information subject to the right of third parties, including obligations of confidentiality between J&J and a third party.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it calls for information, documents, or things regarding "contracts or licenses granting Patriot Pharmaceuticals the right to sell an Authorized Generic; the ownership and control of Patriot Pharmaceuticals; and Janssen Biotech, Inc.'s goals, expectations, and strategy with respect to the sale of Authorized Generics." Such information has no relevance to any disputed matter of law or fact in this case.

Subject to and without waiver of these Specific Objections and the General Objections

above, J&J will produce one or more witnesses to testify generally regarding the actual sales of Authorized Generics by Patriot Pharmaceuticals between November 23, 2018 and December 31, 2020 to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 19: Janssen Biotech, Inc.'s expectations, goals, and strategy with respect to launching a coated version of Zytiga.

RESPONSE TO TOPIC NO. 19: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "expectations," "goals," and "strategy."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case.

J&J will not produce a witness in response to this Topic because it is irrelevant to Relator's claims and too vague, ambiguous, broad, ill-defined, and burdensome to properly prepare a witness.

TOPIC NO. 20: Janssen Biotech, Inc.'s expectations, goals, and strategy with respect to launching a 500 mg version of Zytiga.

RESPONSE TO TOPIC NO. 20: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "expectations," "goals," and "strategy."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation.. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case.

J&J will not produce a witness in response to this Topic because it is irrelevant to Relator's claims and too vague, ambiguous, broad, ill-defined, and burdensome to properly prepare a witness.

TOPIC NO. 21: Any actual or proposed initiatives, studies, or programs to mitigate prednisone coadministration, including, without limitation, the funding or conduct of studies, trials, or other initiatives to explore a reduction in the required dosage for prednisone coadministration, or the substitution of prednisone with another chemical substance when co-administering with Zytiga.

RESPONSE TO TOPIC NO. 21: J&J objects to this Topic as indefinite, vague,

ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "initiatives," "studies," "programs," "mitigate," "funding," "trials," "reduction," "required dosage," "substitution," and "chemical substance."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated for information before J&J's acquisition of Cougar Biotechnology, Inc or after September 2, 2014—the date the '438 Patent issued. J&J also objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J objects to this Topic to the extent it seeks information subject to the rights of third parties, including obligations of confidentiality between any J&J and a third party.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding any studies between July 9, 2009, and September 2, 2014, regarding the administration of abiraterone acetate without prednisone for the treatment of prostate cancer, to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 22: Any efforts to encourage or persuade prescribers, purchases, and the market to accept prednisone coadministration when prescribing Zytiga.

RESPONSE TO TOPIC NO. 22: J&J objects to this Topic as indefinite, vague,

ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "efforts," "encourage," "persuade," "prescribers," "purchasers," "the market," "accept," and "prescribing."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated for information before J&J's acquisition of Cougar Biotechnology, Inc or after September 2, 2014—the date the '438 Patent issued. J&J also objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control.

J&J also objects to the disclosure of commercial, marketing, advertising, regulatory, and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J objects to this Topic to the extent it seeks information subject to the rights of third parties, including obligations of confidentiality between any J&J and a third party.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding J&J's methods of marketing and promoting Zytiga in the United States between July 9, 2009 and September 2, 2014 to the extent that responsive, non-privileged information may have been maintained in the ordinary

course of business and is located after a reasonable search.

TOPIC NO. 23: Janssen Biotech, Inc.'s knowledge concerning the strengths, weaknesses, threats, and opportunities relating to Zytiga compared with actual or potential competitors, including, without limitation, any strategic analysis of Zytiga's competitive position, advantages, and disadvantages against competing treatments.

RESPONSE TO TOPIC NO. 23: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "knowledge," "strengths," "weaknesses," "threats," "opportunities," "actual or potential competitors," "strategic analysis," "competitive position," "advantages," "disadvantages," and "competing treatments."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated for information before J&J's acquisition of Cougar Biotechnology, Inc or after September 2, 2014—the date the '438 Patent issued. J&J also objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control.

J&J further objects to the disclosure of commercial, marketing, advertising, regulatory, and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J objects to this Topic to the extent it seeks information subject to the rights of third parties, including obligations of confidentiality between any J&J and a third party.

J&J also object to this Topic as prematurely seeking expert discovery, and as seeking legal

conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding J&J's methods of marketing and promoting Zytiga in the United States between July 9, 2009 and September 2, 2014, and generally regarding business plans concerning Zytiga between July 9, 2009, and September 2, 2014, to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 24: Janssen Biotech, Inc.'s market share or generic erosion analysis of Zytiga's actual or anticipated market share and sales considering any loss of exclusivity caused by the expiration of regulatory or patent exclusivities.

RESPONSE TO TOPIC NO. 24: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "generic erosion analysis," "sales," "expiration," and "exclusivities."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated for information before J&J's acquisition of Cougar Biotechnology, Inc. or after September 2, 2014—the date the '438 Patent issued. J&J also objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control. J&J also objects to this Topic to the extent it is cumulative to, or duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Discovery Requests Nos. 22 and 25.

J&J further objects to the disclosure of commercial, marketing, advertising, regulatory, and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information

with no relevance to any disputed matter of law or fact in this case.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J objects to this Topic to the extent it seeks information subject to the rights of third parties, including obligations of confidentiality between any J&J and a third party.

J&J also object to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the anticipated timing of market entry of Generic Zytiga and the impact of that entry on Zytiga's sales and market share to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 25: The negotiation and terms of any settlement with generic competitors sued for patent infringement relating to Zytiga.

RESPONSE TO TOPIC NO. 25: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "negotiation," "terms," and "settlement."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation.

J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator,

specifically in response to Relator's Request for Production No. 51.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J further objects to this Topic to the extent it seeks information subject to the rights of third parties, including obligations of confidentiality between J&J and any third party.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because the Topic has no relevance to any disputed matter of law or fact in this case.

J&J will not produce a witness in response to this Topic.

TOPIC NO. 26: The negotiation and terms of any exclusive pharmacy agreements that was intended to, or had the effect of, maintaining or protecting Zytiga's market share against generic competition.

RESPONSE TO TOPIC NO. 26: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "negotiation," "exclusive pharmacy agreements," and "protecting."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J further objects to this Topic to the extent it seeks information subject to the rights

of third parties, including obligations of confidentiality between J&J and any third party.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because the Topic has no relevance to any disputed matter of law or fact in this case.

J&J will not produce a witness in response to this Topic.

Dated: March 2, 2024

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA; STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA, *ex rel*. ZACHARY SILBERSHER, Plaintiffs, v. JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, JOHNSON & JOHNSON, and BTG INTERNATIONAL LIMITED, Defendants.	Civil Action No. 19-12107 (MEF) (ESK) Hon. Michael E. Farbiarz, U.S.D.J. **DEFENDANTS' RESPONSES & OBJECTIONS TO RELATOR'S NOTICE OF 30(b)(6) DEPOSITION OF JANSSEN ONCOLOGY, INC.**

Pursuant to Federal Rules of Civil Procedure 26 and 30, Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson (collectively, "J&J"), by its counsel, hereby respond and object to Relator's Amended Notice of 30(b)(6) Deposition of Janssen Oncology, Inc., dated February 7, 2024 ("Deposition Notice").

GENERAL OBJECTIONS

The following General Objections are generally applicable to each of the Topics. These General Objections are made herein, rather than repeated throughout, to simplify J&J's responses,

and have the same force and effect as if set forth fully in response to each individual Topic. A failure to repeat any portion of these General Objections in any particular response does not constitute a waiver or relinquishment of that objection by J&J.

1. Defendants object to the March 6, 2024 date in the Deposition Notice as unduly burdensome. Defendants will work with Relator to arrive at a mutually agreeable date, time, and location for such a deposition.

2. Defendants object to the Deposition Notice, the Definitions, and each Topic to the extent they impose upon J&J discovery obligations different from, or in addition to, the Federal Rules of Civil Procedure, the Local Civil Rules of the United States District Court for the District of New Jersey, any applicable court order or directive, and/or any stipulation or agreement of the parties.

3. J&J objects to the Deposition Notice to the extent that it fails to comply with either the "reasonable particularity" or "reasonably available to the organization" requirements set forth in Federal Rule of Civil Procedure 30(b)(6).

4. J&J objects to each Topic to the extent that it seeks information that is not within J&J's possession, custody, or control, and can be located following a reasonable search.

5. J&J objects to each Topic to the extent that it seeks discovery that is overly broad, unduly burdensome, not relevant to any claim or defense in this action, and is disproportionate to the needs of the case. For example, J&J objects to each Topic to the extent that it seeks *all* "facts," "issues," or "materials" concerning a particular subject matter.

6. J&J objects to each Topic to the extent that it is duplicative of other discovery taken in this case or seeks discovery that is more easily available through other, less burdensome means.

7. J&J objects to the Deposition Notice and each Topic to the extent they seek

information protected from disclosure by the attorney-client privilege, work product privilege, and/or other any other applicable privilege or protection. The inadvertent disclosure of any such information shall not constitute a waiver of any applicable privilege or immunity.

8. Defendants object to the Deposition Notice to the extent that it seeks information about matters as to which J&J's employees do not have factual knowledge. By stating that it will produce a witness to testify in response to a Topic, J&J does not admit or represent that it has any relevant knowledge or information on that Topic, but instead merely that the designated witness will testify subject to J&J's objections to the extent that non-privileged, relevant knowledge or information on the Topic is reasonably available to J&J and can be located after a reasonable search.

9. J&J objects to each Topic to the extent that it seeks information covered by a confidentiality agreement with a third party.

10. J&J objects to each Topic to the extent that it seeks information protected from disclosure by the constitutional and/or statutory privacy rights of third persons, including HIPAA.

11. J&J objects to each Topic to the extent that it seeks to obtain expert testimony from a lay person or fact witness, or to prematurely obtain expert testimony.

12. Defendants object to each Topic to the extent that it is unlimited in temporal or geographic scope.

13. Defendants object to each Topic to the extent any responsive information has been produced by Relator with designation under Stipulated Amended Discovery Confidentiality Order ("Protective Order") (Dkt. 175), thus precluding Defendants' personnel from reviewing and testifying as to such information.

14. Defendants General and Specific Objections set forth herein are made without

waiver of their right to object on any additional grounds to any of the Topics prior to or during the deposition of any witness taken in response to the Deposition Notice. Further, Defendants' designation of a witness to testify in response to the Deposition Notice is made without waiver of any objections, including as to relevancy, materiality, privilege, or admissibility of any information in this or any subsequent proceeding or at the trial of this or any other action.

OBJECTIONS TO RELATOR'S DEFINITIONS AND INSTRUCTIONS

1. J&J objects to Relator's definition of "Janssen" to as overbroad, unduly burdensome, oppressive, vague and ambiguous, and seeking discovery not relevant to any claim or defense in this action and disproportionate to the needs of the case. Relator's definition of "Janssen" includes entities or persons outside of Janssen's possession, custody, or control, and calls for information that may be subject to confidentiality agreements and/or protected by the attorney-client privilege, work product privilege, or other any other applicable privilege or immunity. J&J is responding on its behalf only and will interpret "Janssen" to refer only to the parties in this action, Janssen Biotech, Inc., Janssen Oncology Inc., Janssen Research & Development, LLC, and Johnson & Johnson.

2. J&J objects to the definition of "Commercial Success Argument" vague, overbroad, unduly burdensome, seeking discovery not relevant to any claim or defense and disproportionate to the needs of the case to the extent it extends to any administrative proceeding or litigation concerning the validity of the '438 Patent. J&J will construe "Commercial Success Argument" to refer to the commercial success argument made to the USPTO during the prosecution of the '340 Application only.

3. Defendants object to the definition of "Zytiga" as vague, overbroad, unduly burdensome, seeking discovery not relevant to any claim or defense and disproportionate to the

needs of the case to the extent it is intended to cover anything other than the abiraterone acetate product and FDA approved uses that are the subject of NDA 202379, and to the extent it is intended to cover any products sold outside the United States.

4. Defendants object insofar as the term "Person" is not used in the Topics.

5. Defendants objects to Relator's Instructions to the extent that they attempt to impose obligations on Defendants different from or in addition to those required by the Stipulated Amended Discovery Confidentiality Order ("Protective Order") (Dkt. 175). In designating witnesses to testify in response to the Deposition Notice, J&J will comply with the Protective Order. Any disclosures made in the context of the Deposition(s) are subject to the Protective Order or any amended versions of such order subsequently entered by the Court.

6. Defendants object to each Topic and Definition to the extent that it contains undefined terms that are subject to multiple interpretations, thus rendering the subject matter vague and ambiguous. To the extent J&J designates witnesses to testify in response to the Deposition Notice, those witnesses will testify based upon J&J's interpretation of undefined terms and understanding of certain terms set forth herein, which may differ from Relators' interpretations.

RESPONSES AND OBJECTIONS TO RELATOR'S TOPICS

TOPIC NO. 1: Defendants' prosecution of all applications leading to the '438 Patent, including the '340 and '440 Applications.

RESPONSE TO TOPIC NO. 1: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "all applications" and "leading to."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation, and calls for information pre-dating J&J's acquisition of Cougar Biotechnology, Inc. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding J&J's prosecution of the '440 Application following its acquisition of Cougar Biotechnology, Inc., and J&J's prosecution of the '340 Application to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 2: Defendants' due diligence relating to the Commercial Success Argument prior to submitting that argument to the Patent Office.

RESPONSE TO TOPIC NO. 2: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the

needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined term "due diligence."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J further objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protections. J&J also objects to this Topic to the extent it is cumulative to, or duplicative of, other discovery or information that has already been provided to Relator.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the commercial success argument presented to the USPTO during the prosecution of the '340 Application to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 3: All facts, issues, and materials that Defendants relied upon or considered in making the Commercial Success Argument.

RESPONSE TO TOPIC NO. 3: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "all," "issues," "materials," "relied upon" and "considered."

J&J further objects to this Topic as overbroad, unduly burdensome, not relevant to any

claim or defense and disproportionate to the needs of this litigation to the extent that it contains no temporal or date limitation. J&J objects to this Topic to the extent it calls for information, documents, or things generated on or after September 2, 2014—the date the '438 Patent issued. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control. J&J also objects to this Topic to the extent it is cumulative to, or duplicative of, other discovery or information that has already been provided to Relator.

J&J further objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, the work-product privilege, and/or any other applicable privilege or immunity.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the commercial success argument presented to the USPTO in connection with the '340 Application to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 4: Defendants' operating procedures, code of ethics, standards, internal guidance, and requirements for any directors, executives, employees, agents, inventors, and patent prosecuting attorneys when prosecuting patent applications.

RESPONSE TO TOPIC NO. 4: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "operating procedures," "standards," "internal guidance" and "requirements."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate

to the needs of this case to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated on or after September 2, 2014—the date the '438 Patent issued.

J&J also objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, the work-product privilege, and/or any other applicable privilege or immunity.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding J&J's policies and procedures applicable to its in-house patent attorneys, and relating to those attorneys' patent prosecution duties, that were in place between July 9, 2009 and December 31, 2014, to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 5: The hierarchy, structure, and responsibilities of the relevant legal and patent prosecution departments for Defendants.

RESPONSE TO TOPIC NO. 5: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "hierarchy," "structure," and "responsibilities."

J&J further objects to this Topic as overbroad, overly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated on or after September 2, 2014—the date the '438 Patent issued.

J&J also objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, the work-product privilege, and/or any other applicable privilege or immunity.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the structure, organization, and responsibilities of the J&J law department's patent prosecution group during the period between July 9, 2009 and December 31, 2014 to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 6: Defendants' sales of Zytiga from 2011 to the present time, including, without limitation, which Defendant entities were involved in making the sale, and transactional details such as the number of units sold, the price per unit, the purchaser, and total sales by date.

RESPONSE TO TOPIC NO. 6: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "sales," "transactional details," "purchaser," and the phrase "without limitation."

J&J further objects to this Topic as overbroad, overly burdensome, and disproportionate to the needs of this case to the extent calls for information, documents, or things generated prior to September 2, 2014—the date the '438 Patent issued.

J&J further objects to the disclosure of commercial, financial, transactional, and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case. J&J also objects to this Topic as

overbroad, unduly burdensome, disproportionate to the needs of this case to the extent it seeks information regarding sales of Zytiga that were not paid for, or reimbursed by, any of the government entities named in the Second Amended Complaint; sales that were not paid for by such government entities have no relevance to any disputed matter of law or fact in this case.

J&J further objects to this Topic to the extent it is cumulative to, or duplicative of, other discovery or information that has already been provided to Relator. J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the sales and pricing data previously produced to Relator in response to Relator's Requests for Production 32, 35, and 36. *See* ZYTIGA_LIT_05587250 - ZYTIGA_LIT_05587253; ZYTIGA_LIT_05597118 - ZYTIGA_LIT_05597123.

TOPIC NO. 7: Defendants' sales of Zytiga from 2011 to the present time to Medicare Plan D sponsors, the Department of Veterans Affairs, Medicaid programs, and Zytiga Specialty Pharmacies for units intended for Government purchase or payment, including, without limitation, which Defendant entities were involved in making the sale, and transactional detail of the number of units sold, the price per unit, the purchaser, and total sales by date.

RESPONSE TO TOPIC NO. 7: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "sales," "Medicaid programs," "intended," "transactional detail," "purchaser," and the phrase "without limitation."

J&J further objects to this Topic as overbroad, overly burdensome, and disproportionate to the needs of this case to the extent calls for information, documents, or things generated prior to September 2, 2014—the date the '438 Patent issued.

J&J also objects to this Topic to the extent that it seeks information that is not within J&J's

possession, custody, or control, or information that is already in Relator's possession, custody, or control. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Relator's Requests for Production No. 32, 35, and 36.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the sales and pricing data previously produced to Relator in response to Relator's Requests for Production 32, 35, and 36. *See* ZYTIGA_LIT_05587250 - ZYTIGA_LIT_05587253; ZYTIGA_LIT_05597118 - ZYTIGA_LIT_05597123.

TOPIC NO. 8: Defendants' prices, including rebates or similar reimbursements, for Zytiga to any government purchaser or payor for Zytiga from 2011 to the present time, including, without limitation, the setting of prices, and the calculation of rebates or similar reimbursements.

RESPONSE TO TOPIC NO. 8: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "rebates," "similar reimbursements," "government purchaser or payor," and "setting of prices."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent calls for information, documents, or things generated prior to September 2, 2014—the date the '438 Patent issued.

J&J objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control, or information that is already in Relator's possession, custody, or

control. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Relator's Requests for Production Nos. 32, 35, and 36.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the sales and pricing data previously produced to Relator in response to Relator's Requests for Production 32, 35, and 36. *See* ZYTIGA_LIT_05587250 - ZYTIGA_LIT_05587253; ZYTIGA_LIT_05597118 - ZYTIGA_LIT_05597123.

TOPIC NO. 9: Defendants' agreements with Medicare Plan D sponsors, the Department of Veterans Affairs, and the Department of Health & Human Services (including the Centers for Medicare & Medicaid Services) for Zytiga from 2011 to the present time.

RESPONSE TO TOPIC NO. 9: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined term "agreements."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent calls for information, documents, or things generated prior to September 2, 2014—the date the '438 Patent issued.

J&J objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control, or information that is already in Relator's possession, custody, or control. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Relator's Request for Production No. 31.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the terms of the final, written contracts and/or written amendments between J&J and government-funded health plans or programs, or other governmental entity purchases that were previously produced in response to Relator's Requests for Production. *See* ZYTIGA_LIT_05415095 - ZYTIGA_LIT_05418027.

TOPIC NO. 10: The listing of Zytiga in the Federal Supply Schedule.

RESPONSE TO TOPIC NO. 10: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined term "listing."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated prior to September 2, 2014—the date the '438 Patent issued. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J further objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the listing of Zytiga in the Federal Supply Schedule following the issuance of the '438 Patent to the extent that

responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 11: The listing of the '438 Patent in the Orange Book (the U.S. Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations), and the subsequent institution of patent litigation against generic competitors.

RESPONSE TO TOPIC NO. 11: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined term "listing."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation.

J&J further objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J also objects to this Topic to the extent it is cumulative to, or duplicative of, other discovery or information that has already been provided to Relator.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it calls for information, documents, or things regarding "the subsequent institution of patent litigation against generic competitors." Such information has no relevance to any disputed matter of law or fact in this case, at least in part because the Court previously rejected the claim that the underlying patent infringement litigation was a "sham."

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the decision to list, or continue to list, the '438 Patent in the FDA's Orange Book to the extent that responsive, non-

privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 12: The roles, Rights, and responsibilities of Janssen Oncology, Inc in the research, development, manufacture, marketing, or sale of Zytiga.

RESPONSE TO TOPIC NO. 12: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "roles," "responsibilities," and "development."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation. J&J further objects to the disclosure of commercial and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

J&J will not produce a witness in response to this Topic, which is too vague, ambiguous, broad, ill-defined, and burdensome to properly prepare a witness.

TOPIC NO. 13: The role, Rights, and responsibilities of Janssen Oncology, Inc. relating to the '340 Application, the '440 Application, the '213 Patent, and the '438 Patent.

RESPONSE TO TOPIC NO. 13: J&J objects to this Topic as indefinite, vague,

ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "roles," and "responsibilities."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, in particular in response to Topics 1, 2, and 3.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

J&J will not produce a witness in response to this Topic, which is too vague, ambiguous, broad, ill-defined, and burdensome to properly prepare a witness. To the extent this Topic is relevant to Relator's claims, it is duplicative of other Topics for which J&J has produced a witness, including Topics 1, 2, and 3.

TOPIC NO. 14: The acquisition, license, or transfer of any Rights related to the '213 Patent.

RESPONSE TO TOPIC NO. 14: J&J objects to this Topic as overly broad, unduly burdensome, indefinite, vague and ambiguous, seeking information that is neither relevant to a claim or defense in this action nor proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "acquisition," "license," and "transfer."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent that it seeks

information that is not within J&J's possession, custody, or control, or information that is already in Relator's possession, custody, or control. J&J also objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Relator's Request for Production No. 53.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J also objects to this Topic to the extent it seeks information subject to the right of third parties, including obligations of confidentiality between J&J and a third party.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify regarding the license agreement between J&J and BTG concerning the '213 Patent to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 15: The acquisition, license, or transfer of any Rights related to the '438 Patent.

RESPONSE TO TOPIC NO. 15: J&J objects to this Topic as overly broad, unduly burdensome, indefinite, vague and ambiguous, seeking information that is neither relevant to a claim or defense in this action nor proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "acquisition," "license," and "transfer."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control, or information that is already

in Relator's possession, custody, or control. J&J also objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Relator's Request for Production No. 53.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J also objects to this Topic to the extent it seeks information subject to the right of third parties, including obligations of confidentiality between J&J and a third party.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case.

J&J will not produce a witness in response to this Topic, which is irrelevant to Relator's claims and too vague, ambiguous, broad, ill-defined, irrelevant and burdensome to properly prepare a witness.

TOPIC NO. 16: Any actions taken by Janssen Oncology, Inc. to enforce the '438 Patent, and any benefits derived by Janssen Oncology, Inc. from enforcement of the '438 patent.

RESPONSE TO TOPIC NO. 16: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the terms "action," "enforce," "benefits," and "enforcement."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or

control, information that is publicly available, or information that is already in Relator's possession, custody, or control. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, in particular in response to Topic 11.

J&J further objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

J&J objects to this Topic as unduly burdensome on the ground that it seeks information regarding highly confidential commercial documents and/or communications with no relevance to any disputed matter of law or fact in this case, at least in part because the Court previously rejected any claim that the underlying patent infringement litigation was a "sham."

J&J will not provide a witness for this topic because this Topic is irrelevant to Relator's claims and too broad, burdensome, and ill-defined to properly prepare a witness.

TOPIC NO. 17: Any actions taken by Janssen Oncology, Inc. related to the '340 Application and the '440 Application.

RESPONSE TO TOPIC NO. 17: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined term "actions."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation, and calls for information pre-dating J&J's acquisition of Cougar Biotechnology, Inc. J&J further objects to this

Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control. J&J also objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, in particular in response to Topic 1, 2, and 3.

J&J further objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection .

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information on highly confidential commercial documents and/or communications with no relevance to any disputed matter of law or fact in this case, at least in part because the Court previously ruled against any claim that the underlying patent infringement litigation was a "sham."

J&J will not provide a witness for this topic because this Topic is irrelevant to Relator's claims and too broad, burdensome, and ill-defined to properly prepare a witness. To this extent this Topic is relevant to Relator's claims it is duplicative of Topics for which J&J has provided a witness, including Topics 1, 2, and 3.

TOPIC NO. 18: The sale of any Authorized Generic of Zytiga, including, without limitation, any contracts or licenses granting Patriot Pharmaceuticals the right to sell an Authorized Generic; the ownership and control of Patriot Pharmaceuticals; and Janssen Oncology, Inc.'s goals, expectations, and strategy with respect to the sale of Authorized Generics.

RESPONSE TO TOPIC NO. 18: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "sale," "contracts," "licenses," "right," "sell,"

"ownership," "control," "goals," "expectations," and "strategy."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J further objects to the disclosure of commercial, financial, transactional, and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, disproportionate to the needs of this case, and not relevant to any disputed issue of law or fact.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J also objects to this Topic to the extent it seeks information subject to the right of third parties, including obligations of confidentiality between J&J and a third party.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it calls for information, documents, or things regarding "contracts or licenses granting Patriot Pharmaceuticals the right to sell an Authorized Generic; the ownership and control of Patriot Pharmaceuticals; and Janssen Oncology, Inc.'s goals, expectations, and strategy with respect to the sale of Authorized Generics." Such information has no relevance to any disputed matter of law or fact in this case.

Subject to and without waiver of these Specific Objections and the General Objections

above, J&J will produce one or more witnesses to testify generally regarding the actual sales of Authorized Generics by Patriot Pharmaceuticals between November 23, 2018 and December 31, 2020 to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 19: Janssen Oncology, Inc.'s expectations, goals, and strategy with respect to launching a coated version of Zytiga.

RESPONSE TO TOPIC NO. 19: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "expectations," "goals," and "strategy."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case.

J&J will not produce a witness in response to this Topic because it is irrelevant to Relator's claims and too vague, ambiguous, broad, ill-defined, and burdensome to properly prepare a witness.

TOPIC NO. 20: Janssen Oncology, Inc.'s expectations, goals, and strategy with respect to launching a 500 mg version of Zytiga.

RESPONSE TO TOPIC NO. 20: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "expectations," "goals," and "strategy."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation.. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case.

J&J will not produce a witness in response to this Topic because it is irrelevant to Relator's claims and too vague, ambiguous, broad, ill-defined, and burdensome to properly prepare a witness.

TOPIC NO. 21: Any actual or proposed initiatives, studies, or programs to mitigate prednisone coadministration, including, without limitation, the funding or conduct of studies, trials, or other initiatives to explore a reduction in the required dosage for prednisone coadministration, or the substitution of prednisone with another chemical substance when co-administering with Zytiga.

RESPONSE TO TOPIC NO. 21: J&J objects to this Topic as indefinite, vague,

ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "initiatives," "studies," "programs," "mitigate," "funding," "trials," "reduction," "required dosage," "substitution," and "chemical substance."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated for information before J&J's acquisition of Cougar Biotechnology, Inc or after September 2, 2014—the date the '438 Patent issued. J&J also objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J objects to this Topic to the extent it seeks information subject to the rights of third parties, including obligations of confidentiality between any J&J and a third party.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding any studies between July 9, 2009, and September 2, 2014, regarding the administration of abiraterone acetate without prednisone for the treatment of prostate cancer, to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 22: Any efforts to encourage or persuade prescribers, purchases, and the market to accept prednisone coadministration when prescribing Zytiga.

RESPONSE TO TOPIC NO. 22: J&J objects to this Topic as indefinite, vague,

ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "efforts," "encourage," "persuade," "prescribers," "purchasers," "the market," "accept," and "prescribing."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated for information before J&J's acquisition of Cougar Biotechnology, Inc or after September 2, 2014—the date the '438 Patent issued. J&J also objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control.

J&J also objects to the disclosure of commercial, marketing, advertising, regulatory, and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J objects to this Topic to the extent it seeks information subject to the rights of third parties, including obligations of confidentiality between any J&J and a third party.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding J&J's methods of marketing and promoting Zytiga in the United States between July 9, 2009 and September 2, 2014 to the extent that responsive, non-privileged information may have been maintained in the ordinary

course of business and is located after a reasonable search.

TOPIC NO. 23: Janssen Oncology, Inc.'s knowledge concerning the strengths, weaknesses, threats, and opportunities relating to Zytiga compared with actual or potential competitors, including, without limitation, any strategic analysis of Zytiga's competitive position, advantages, and disadvantages against competing treatments.

RESPONSE TO TOPIC NO. 23: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "knowledge," "strengths," "weaknesses," "threats," "opportunities," "actual or potential competitors," "strategic analysis," "competitive position," "advantages," "disadvantages," and "competing treatments."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated for information before J&J's acquisition of Cougar Biotechnology, Inc or after September 2, 2014—the date the '438 Patent issued. J&J also objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control.

J&J further objects to the disclosure of commercial, marketing, advertising, regulatory, and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J objects to this Topic to the extent it seeks information subject to the rights of third parties, including obligations of confidentiality between any J&J and a third party.

J&J also object to this Topic as prematurely seeking expert discovery, and as seeking legal

conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding J&J's methods of marketing and promoting Zytiga in the United States between July 9, 2009 and September 2, 2014, and generally regarding business plans concerning Zytiga between July 9, 2009, and September 2, 2014, to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 24: Janssen Oncology, Inc.'s market share or generic erosion analysis of Zytiga's actual or anticipated market share and sales considering any loss of exclusivity caused by the expiration of regulatory or patent exclusivities.

RESPONSE TO TOPIC NO. 24: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "generic erosion analysis," "sales," "expiration," and "exclusivities."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated for information before J&J's acquisition of Cougar Biotechnology, Inc. or after September 2, 2014—the date the '438 Patent issued. J&J also objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control. J&J also objects to this Topic to the extent it is cumulative to, or duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Discovery Requests Nos. 22 and 25.

J&J further objects to the disclosure of commercial, marketing, advertising, regulatory, and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information

with no relevance to any disputed matter of law or fact in this case.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J objects to this Topic to the extent it seeks information subject to the rights of third parties, including obligations of confidentiality between any J&J and a third party.

J&J also object to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the anticipated timing of market entry of Generic Zytiga and the impact of that entry on Zytiga's sales and market share to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 25: The negotiation and terms of any settlement with generic competitors sued for patent infringement relating to Zytiga.

RESPONSE TO TOPIC NO. 25: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "negotiation," "terms," and "settlement."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation.

J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator,

specifically in response to Relator's Request for Production No. 51.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J further objects to this Topic to the extent it seeks information subject to the rights of third parties, including obligations of confidentiality between J&J and any third party.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because the Topic has no relevance to any disputed matter of law or fact in this case.

J&J will not produce a witness in response to this Topic.

TOPIC NO. 26: The negotiation and terms of any exclusive pharmacy agreements that was intended to, or had the effect of, maintaining or protecting Zytiga's market share against generic competition.

RESPONSE TO TOPIC NO. 26: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "negotiation," "exclusive pharmacy agreements," and "protecting."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J further objects to this Topic to the extent it seeks information subject to the rights

of third parties, including obligations of confidentiality between J&J and any third party.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because the Topic has no relevance to any disputed matter of law or fact in this case.

J&J will not produce a witness in response to this Topic.

Dated: March 2, 2024

By: *Jeffrey J. Greenbaum*

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA; STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA, *ex rel*. ZACHARY SILBERSHER, Plaintiffs, v. JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, JOHNSON & JOHNSON, and BTG INTERNATIONAL LIMITED, Defendants.	Civil Action No. 19-12107 (MEF) (ESK) Hon. Michael E. Farbiarz, U.S.D.J. **DEFENDANTS' RESPONSES & OBJECTIONS TO RELATOR'S NOTICE OF 30(b)(6) DEPOSITION OF JANSSEN RESEARCH & DEVELOPMENT LLC**

Pursuant to Federal Rules of Civil Procedure 26 and 30, Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson (collectively, "J&J"), by its counsel, hereby respond and object to Relator's Amended Notice of 30(b)(6) Deposition of Janssen Research & Development, LLC, dated February 7, 2024 ("Deposition Notice").

GENERAL OBJECTIONS

The following General Objections are generally applicable to each of the Topics. These

General Objections are made herein, rather than repeated throughout, to simplify J&J's responses, and have the same force and effect as if set forth fully in response to each individual Topic. A failure to repeat any portion of these General Objections in any particular response does not constitute a waiver or relinquishment of that objection by J&J.

1. Defendants object to the March 6, 2024 date in the Deposition Notice as unduly burdensome. Defendants will work with Relator to arrive at a mutually agreeable date, time, and location for such a deposition.

2. Defendants object to the Deposition Notice, the Definitions, and each Topic to the extent they impose upon J&J discovery obligations different from, or in addition to, the Federal Rules of Civil Procedure, the Local Civil Rules of the United States District Court for the District of New Jersey, any applicable court order or directive, and/or any stipulation or agreement of the parties.

3. J&J objects to the Deposition Notice to the extent that it fails to comply with either the "reasonable particularity" or "reasonably available to the organization" requirements set forth in Federal Rule of Civil Procedure 30(b)(6).

4. J&J objects to each Topic to the extent that it seeks information that is not within J&J's possession, custody, or control, and can be located following a reasonable search.

5. J&J objects to each Topic to the extent that it seeks discovery that is overly broad, unduly burdensome, not relevant to any claim or defense in this action, and is disproportionate to the needs of the case. For example, J&J objects to each Topic to the extent that it seeks *all* "facts," "issues," or "materials" concerning a particular subject matter.

6. J&J objects to each Topic to the extent that it is duplicative of other discovery taken in this case or seeks discovery that is more easily available through other, less burdensome means.

7. J&J objects to the Deposition Notice and each Topic to the extent they seek information protected from disclosure by the attorney-client privilege, work product privilege, and/or other any other applicable privilege or protection. The inadvertent disclosure of any such information shall not constitute a waiver of any applicable privilege or immunity.

8. Defendants object to the Deposition Notice to the extent that it seeks information about matters as to which J&J's employees do not have factual knowledge. By stating that it will produce a witness to testify in response to a Topic, J&J does not admit or represent that it has any relevant knowledge or information on that Topic, but instead merely that the designated witness will testify subject to J&J's objections to the extent that non-privileged, relevant knowledge or information on the Topic is reasonably available to J&J and can be located after a reasonable search.

9. J&J objects to each Topic to the extent that it seeks information covered by a confidentiality agreement with a third party.

10. J&J objects to each Topic to the extent that it seeks information protected from disclosure by the constitutional and/or statutory privacy rights of third persons, including HIPAA.

11. J&J objects to each Topic to the extent that it seeks to obtain expert testimony from a lay person or fact witness, or to prematurely obtain expert testimony.

12. Defendants object to each Topic to the extent that it is unlimited in temporal or geographic scope.

13. Defendants object to each Topic to the extent any responsive information has been produced by Relator with designation under Stipulated Amended Discovery Confidentiality Order ("Protective Order") (Dkt. 175), thus precluding Defendants' personnel from reviewing and testifying as to such information.

14. Defendants General and Specific Objections set forth herein are made without waiver of their right to object on any additional grounds to any of the Topics prior to or during the deposition of any witness taken in response to the Deposition Notice. Further, Defendants' designation of a witness to testify in response to the Deposition Notice is made without waiver of any objections, including as to relevancy, materiality, privilege, or admissibility of any information in this or any subsequent proceeding or at the trial of this or any other action.

OBJECTIONS TO RELATOR'S DEFINITIONS AND INSTRUCTIONS

1. J&J objects to Relator's definition of "Janssen" to as overbroad, unduly burdensome, oppressive, vague and ambiguous, and seeking discovery not relevant to any claim or defense in this action and disproportionate to the needs of the case. Relator's definition of "Janssen" includes entities or persons outside of Janssen's possession, custody, or control, and calls for information that may be subject to confidentiality agreements and/or protected by the attorney-client privilege, work product privilege, or other any other applicable privilege or immunity. J&J is responding on its behalf only and will interpret "Janssen" to refer only to the parties in this action, Janssen Biotech, Inc., Janssen Oncology Inc., Janssen Research & Development, LLC, and Johnson & Johnson.

2. J&J objects to the definition of "Commercial Success Argument" vague, overbroad, unduly burdensome, seeking discovery not relevant to any claim or defense and disproportionate to the needs of the case to the extent it extends to any administrative proceeding or litigation concerning the validity of the '438 Patent. J&J will construe "Commercial Success Argument" to refer to the commercial success argument made to the USPTO during the prosecution of the '340 Application only.

3. Defendants object to the definition of "Zytiga" as vague, overbroad, unduly

burdensome, seeking discovery not relevant to any claim or defense and disproportionate to the needs of the case to the extent it is intended to cover anything other than the abiraterone acetate product and FDA approved uses that are the subject of NDA 202379, and to the extent it is intended to cover any products sold outside the United States.

4. Defendants object insofar as the term "Person" is not used in the Topics.

5. Defendants objects to Relator's Instructions to the extent that they attempt to impose obligations on Defendants different from or in addition to those required by the Stipulated Amended Discovery Confidentiality Order ("Protective Order") (Dkt. 175). In designating witnesses to testify in response to the Deposition Notice, J&J will comply with the Protective Order. Any disclosures made in the context of the Deposition(s) are subject to the Protective Order or any amended versions of such order subsequently entered by the Court.

6. Defendants object to each Topic and Definition to the extent that it contains undefined terms that are subject to multiple interpretations, thus rendering the subject matter vague and ambiguous. To the extent J&J designates witnesses to testify in response to the Deposition Notice, those witnesses will testify based upon J&J's interpretation of undefined terms and understanding of certain terms set forth herein, which may differ from Relators' interpretations.

RESPONSES AND OBJECTIONS TO RELATOR'S TOPICS

TOPIC NO. 1: Defendants' prosecution of all applications leading to the '438 Patent, including the '340 and '440 Applications.

RESPONSE TO TOPIC NO. 1: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "all applications" and "leading to."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation, and calls for information pre-dating J&J's acquisition of Cougar Biotechnology, Inc. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding J&J's prosecution of the '440 Application following its acquisition of Cougar Biotechnology, Inc., and J&J's prosecution of the '340 Application to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 2: Defendants' due diligence relating to the Commercial Success Argument prior to submitting that argument to the Patent Office.

RESPONSE TO TOPIC NO. 2: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the

needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined term "due diligence."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J further objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protections. J&J also objects to this Topic to the extent it is cumulative to, or duplicative of, other discovery or information that has already been provided to Relator.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the commercial success argument presented to the USPTO during the prosecution of the '340 Application to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 3: All facts, issues, and materials that Defendants relied upon or considered in making the Commercial Success Argument.

RESPONSE TO TOPIC NO. 3: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "all," "issues," "materials," "relied upon" and "considered."

J&J further objects to this Topic as overbroad, unduly burdensome, not relevant to any

claim or defense and disproportionate to the needs of this litigation to the extent that it contains no temporal or date limitation. J&J objects to this Topic to the extent it calls for information, documents, or things generated on or after September 2, 2014—the date the '438 Patent issued. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control. J&J also objects to this Topic to the extent it is cumulative to, or duplicative of, other discovery or information that has already been provided to Relator.

J&J further objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, the work-product privilege, and/or any other applicable privilege or immunity.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the commercial success argument presented to the USPTO in connection with the '340 Application to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 4: Defendants' operating procedures, code of ethics, standards, internal guidance, and requirements for any directors, executives, employees, agents, inventors, and patent prosecuting attorneys when prosecuting patent applications.

RESPONSE TO TOPIC NO. 4: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "operating procedures," "standards," "internal guidance" and "requirements."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate

to the needs of this case to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated on or after September 2, 2014—the date the '438 Patent issued.

J&J also objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, the work-product privilege, and/or any other applicable privilege or immunity.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding J&J's policies and procedures applicable to its in-house patent attorneys, and relating to those attorneys' patent prosecution duties, that were in place between July 9, 2009 and December 31, 2014, to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 5: The hierarchy, structure, and responsibilities of the relevant legal and patent prosecution departments for Defendants.

RESPONSE TO TOPIC NO. 5: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "hierarchy," "structure," and "responsibilities."

J&J further objects to this Topic as overbroad, overly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated on or after September 2, 2014—the date the '438 Patent issued.

J&J also objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, the work-product privilege, and/or any other applicable privilege or immunity.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the structure, organization, and responsibilities of the J&J law department's patent prosecution group during the period between July 9, 2009 and December 31, 2014 to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 6: Defendants' sales of Zytiga from 2011 to the present time, including, without limitation, which Defendant entities were involved in making the sale, and transactional details such as the number of units sold, the price per unit, the purchaser, and total sales by date.

RESPONSE TO TOPIC NO. 6: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "sales," "transactional details," "purchaser," and the phrase "without limitation."

J&J further objects to this Topic as overbroad, overly burdensome, and disproportionate to the needs of this case to the extent calls for information, documents, or things generated prior to September 2, 2014—the date the '438 Patent issued.

J&J further objects to the disclosure of commercial, financial, transactional, and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case. J&J also objects to this Topic as

overbroad, unduly burdensome, disproportionate to the needs of this case to the extent it seeks information regarding sales of Zytiga that were not paid for, or reimbursed by, any of the government entities named in the Second Amended Complaint; sales that were not paid for by such government entities have no relevance to any disputed matter of law or fact in this case.

J&J further objects to this Topic to the extent it is cumulative to, or duplicative of, other discovery or information that has already been provided to Relator. J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the sales and pricing data previously produced to Relator in response to Relator's Requests for Production 32, 35, and 36. *See* ZYTIGA_LIT_05587250 - ZYTIGA_LIT_05587253; ZYTIGA_LIT_05597118 - ZYTIGA_LIT_05597123.

TOPIC NO. 7: Defendants' sales of Zytiga from 2011 to the present time to Medicare Plan D sponsors, the Department of Veterans Affairs, Medicaid programs, and Zytiga Specialty Pharmacies for units intended for Government purchase or payment, including, without limitation, which Defendant entities were involved in making the sale, and transactional detail of the number of units sold, the price per unit, the purchaser, and total sales by date.

RESPONSE TO TOPIC NO. 7: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "sales," "Medicaid programs," "intended," "transactional detail," "purchaser," and the phrase "without limitation."

J&J further objects to this Topic as overbroad, overly burdensome, and disproportionate to the needs of this case to the extent calls for information, documents, or things generated prior to September 2, 2014—the date the '438 Patent issued.

J&J also objects to this Topic to the extent that it seeks information that is not within J&J's

possession, custody, or control, or information that is already in Relator's possession, custody, or control. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Relator's Requests for Production No. 32, 35, and 36.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the sales and pricing data previously produced to Relator in response to Relator's Requests for Production 32, 35, and 36. *See* ZYTIGA_LIT_05587250 - ZYTIGA_LIT_05587253; ZYTIGA_LIT_05597118 - ZYTIGA_LIT_05597123.

TOPIC NO. 8: Defendants' prices, including rebates or similar reimbursements, for Zytiga to any government purchaser or payor for Zytiga from 2011 to the present time, including, without limitation, the setting of prices, and the calculation of rebates or similar reimbursements.

RESPONSE TO TOPIC NO. 8: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "rebates," "similar reimbursements," "government purchaser or payor," and "setting of prices."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent calls for information, documents, or things generated prior to September 2, 2014—the date the '438 Patent issued.

J&J objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control, or information that is already in Relator's possession, custody, or

control. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Relator's Requests for Production Nos. 32, 35, and 36.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the sales and pricing data previously produced to Relator in response to Relator's Requests for Production 32, 35, and 36. *See* ZYTIGA_LIT_05587250 - ZYTIGA_LIT_05587253; ZYTIGA_LIT_05597118 - ZYTIGA_LIT_05597123.

TOPIC NO. 9: Defendants' agreements with Medicare Plan D sponsors, the Department of Veterans Affairs, and the Department of Health & Human Services (including the Centers for Medicare & Medicaid Services) for Zytiga from 2011 to the present time.

RESPONSE TO TOPIC NO. 9: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined term "agreements."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent calls for information, documents, or things generated prior to September 2, 2014—the date the '438 Patent issued.

J&J objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control, or information that is already in Relator's possession, custody, or control. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Relator's Request for Production No. 31.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the terms of the final, written contracts and/or written amendments between J&J and government-funded health plans or programs, or other governmental entity purchases that were previously produced in response to Relator's Requests for Production. *See* ZYTIGA_LIT_05415095 - ZYTIGA_LIT_05418027.

TOPIC NO. 10: The listing of Zytiga in the Federal Supply Schedule.

RESPONSE TO TOPIC NO. 10: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined term "listing."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated prior to September 2, 2014—the date the '438 Patent issued. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J further objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the listing of Zytiga in the Federal Supply Schedule following the issuance of the '438 Patent to the extent that

responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 11: The listing of the '438 Patent in the Orange Book (the U.S. Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations), and the subsequent institution of patent litigation against generic competitors.

RESPONSE TO TOPIC NO. 11: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined term "listing."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation.

J&J further objects to this Topic to the extent it requests information, documents, and/or materials protected by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J also objects to this Topic to the extent it is cumulative to, or duplicative of, other discovery or information that has already been provided to Relator.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it calls for information, documents, or things regarding "the subsequent institution of patent litigation against generic competitors." Such information has no relevance to any disputed matter of law or fact in this case, at least in part because the Court previously rejected the claim that the underlying patent infringement litigation was a "sham."

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the decision to list, or continue to list, the '438 Patent in the FDA's Orange Book to the extent that responsive, non-

privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 12: The roles, Rights, and responsibilities of Janssen Research & Development, LLC, in the research, development, manufacture, marketing, or sale of Zytiga.

RESPONSE TO TOPIC NO. 12: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "roles," "responsibilities," and "development."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation. J&J further objects to the disclosure of commercial and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

J&J will not produce a witness in response to this Topic, which is too vague, ambiguous, broad, ill-defined, and burdensome to properly prepare a witness.

TOPIC NO. 13: The role, Rights, and responsibilities of Janssen Research & Development, LLC, relating to the '340 Application, the '440 Application, the '213 Patent, and the '438 Patent.

RESPONSE TO TOPIC NO. 13: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "roles," and "responsibilities."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, in particular in response to Topics 1, 2, and 3.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

J&J will not produce a witness in response to this Topic, which is too vague, ambiguous, broad, ill-defined, and burdensome to properly prepare a witness. To the extent this Topic is relevant to Relator's claims, it is duplicative of other Topics for which J&J has produced a witness, including Topics 1, 2, and 3.

TOPIC NO. 14: The acquisition, license, or transfer of any Rights related to the '213 Patent.

RESPONSE TO TOPIC NO. 14: J&J objects to this Topic as overly broad, unduly burdensome, indefinite, vague and ambiguous, seeking information that is neither relevant to a claim or defense in this action nor proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined

terms "acquisition," "license," and "transfer."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control, or information that is already in Relator's possession, custody, or control. J&J also objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Relator's Request for Production No. 53.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J also objects to this Topic to the extent it seeks information subject to the right of third parties, including obligations of confidentiality between J&J and a third party.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify regarding the license agreement between J&J and BTG concerning the '213 Patent to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 15: The acquisition, license, or transfer of any Rights related to the '438 Patent.

RESPONSE TO TOPIC NO. 15: J&J objects to this Topic as overly broad, unduly burdensome, indefinite, vague and ambiguous, seeking information that is neither relevant to a claim or defense in this action nor proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "acquisition," "license," and "transfer."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control, or information that is already in Relator's possession, custody, or control. J&J also objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Relator's Request for Production No. 53.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J also objects to this Topic to the extent it seeks information subject to the right of third parties, including obligations of confidentiality between J&J and a third party.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case.

J&J will not produce a witness in response to this Topic, which is irrelevant to Relator's claims and too vague, ambiguous, broad, ill-defined, irrelevant and burdensome to properly prepare a witness.

TOPIC NO. 16: Any actions taken by Janssen Research & Development, LLC, to enforce the '438 Patent, and any benefits derived by Janssen Research & Development, LLC, from enforcement of the '438 patent.

RESPONSE TO TOPIC NO. 16: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the terms "action," "enforce," "benefits," and "enforcement."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, in particular in response to Topic 11.

J&J further objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

J&J objects to this Topic as unduly burdensome on the ground that it seeks information regarding highly confidential commercial documents and/or communications with no relevance to any disputed matter of law or fact in this case, at least in part because the Court previously rejected any claim that the underlying patent infringement litigation was a "sham."

J&J will not provide a witness for this topic because this Topic is irrelevant to Relator's claims and too broad, burdensome, and ill-defined to properly prepare a witness.

TOPIC NO. 17: Any actions taken by Janssen Research & Development, LLC, related to the '340 Application and the '440 Application.

RESPONSE TO TOPIC NO. 17: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination,

for example, in its use of the undefined term "actions."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation, and calls for information pre-dating J&J's acquisition of Cougar Biotechnology, Inc. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control. J&J also objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, in particular in response to Topic 1, 2, and 3.

J&J further objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection .

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information on highly confidential commercial documents and/or communications with no relevance to any disputed matter of law or fact in this case, at least in part because the Court previously ruled against any claim that the underlying patent infringement litigation was a "sham."

J&J will not provide a witness for this topic because this Topic is irrelevant to Relator's claims and too broad, burdensome, and ill-defined to properly prepare a witness. To this extent this Topic is relevant to Relator's claims it is duplicative of Topics for which J&J has provided a witness, including Topics 1, 2, and 3.

TOPIC NO. 18: The sale of any Authorized Generic of Zytiga, including, without limitation, any contracts or licenses granting Patriot Pharmaceuticals the right to sell an Authorized Generic; the ownership and control of Patriot Pharmaceuticals; and Janssen Research & Development, LLC's goals, expectations, and strategy with respect to the sale of Authorized Generics.

RESPONSE TO TOPIC NO. 18: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "sale," "contracts," "licenses," "right," "sell," "ownership," "control," "goals," "expectations," and "strategy."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J further objects to the disclosure of commercial, financial, transactional, and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, disproportionate to the needs of this case, and not relevant to any disputed issue of law or fact.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J also objects to this Topic to the extent it seeks information subject to the right of third parties, including obligations of confidentiality between J&J and a third party.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to

the needs of this case to the extent it calls for information, documents, or things regarding "contracts or licenses granting Patriot Pharmaceuticals the right to sell an Authorized Generic; the ownership and control of Patriot Pharmaceuticals; and Janssen Research & Development, LLC's goals, expectations, and strategy with respect to the sale of Authorized Generics." Such information has no relevance to any disputed matter of law or fact in this case.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the actual sales of Authorized Generics by Patriot Pharmaceuticals between November 23, 2018 and December 31, 2020 to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 19: Janssen Research & Development, LLC,'s expectations, goals, and strategy with respect to launching a coated version of Zytiga.

RESPONSE TO TOPIC NO. 19: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "expectations," "goals," and "strategy."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case.

J&J will not produce a witness in response to this Topic because it is irrelevant to Relator's claims and too vague, ambiguous, broad, ill-defined, and burdensome to properly prepare a witness.

TOPIC NO. 20: Janssen Research & Development, LLC,'s expectations, goals, and strategy with respect to launching a 500 mg version of Zytiga.

RESPONSE TO TOPIC NO. 20: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "expectations," "goals," and "strategy."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation.. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case.

J&J will not produce a witness in response to this Topic because it is irrelevant to Relator's

claims and too vague, ambiguous, broad, ill-defined, and burdensome to properly prepare a witness.

TOPIC NO. 21: Any actual or proposed initiatives, studies, or programs to mitigate prednisone coadministration, including, without limitation, the funding or conduct of studies, trials, or other initiatives to explore a reduction in the required dosage for prednisone coadministration, or the substitution of prednisone with another chemical substance when co-administering with Zytiga.

RESPONSE TO TOPIC NO. 21: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "initiatives," "studies," "programs," "mitigate," "funding," "trials," "reduction," "required dosage," "substitution," and "chemical substance."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated for information before J&J's acquisition of Cougar Biotechnology, Inc or after September 2, 2014—the date the '438 Patent issued. J&J also objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J objects to this Topic to the extent it seeks information subject to the rights of third parties, including obligations of confidentiality between any J&J and a third party.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding any studies between July 9, 2009, and September 2, 2014, regarding the administration of abiraterone acetate without

prednisone for the treatment of prostate cancer, to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 22: Any efforts to encourage or persuade prescribers, purchases, and the market to accept prednisone coadministration when prescribing Zytiga.

RESPONSE TO TOPIC NO. 22: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "efforts," "encourage," "persuade," "prescribers," "purchasers," "the market," "accept," and "prescribing."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated for information before J&J's acquisition of Cougar Biotechnology, Inc or after September 2, 2014—the date the '438 Patent issued. J&J also objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control.

J&J also objects to the disclosure of commercial, marketing, advertising, regulatory, and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J objects to this Topic to the extent it seeks information subject to the rights of third parties, including obligations of confidentiality between any J&J and a third party.

J&J also objects to this Topic as prematurely seeking expert discovery, and as seeking legal

conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding J&J's methods of marketing and promoting Zytiga in the United States between July 9, 2009 and September 2, 2014 to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 23: Janssen Research & Development, LLC,'s knowledge concerning the strengths, weaknesses, threats, and opportunities relating to Zytiga compared with actual or potential competitors, including, without limitation, any strategic analysis of Zytiga's competitive position, advantages, and disadvantages against competing treatments.

RESPONSE TO TOPIC NO. 23: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "knowledge," "strengths," "weaknesses," "threats," "opportunities," "actual or potential competitors," "strategic analysis," "competitive position," "advantages," "disadvantages," and "competing treatments."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated for information before J&J's acquisition of Cougar Biotechnology, Inc or after September 2, 2014—the date the '438 Patent issued. J&J also objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control.

J&J further objects to the disclosure of commercial, marketing, advertising, regulatory, and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J objects to this Topic to the extent it seeks information subject to the rights of third parties, including obligations of confidentiality between any J&J and a third party.

J&J also object to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding J&J's methods of marketing and promoting Zytiga in the United States between July 9, 2009 and September 2, 2014, and generally regarding business plans concerning Zytiga between July 9, 2009, and September 2, 2014, to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 24: Janssen Research & Development, LLC,'s market share or generic erosion analysis of Zytiga's actual or anticipated market share and sales considering any loss of exclusivity caused by the expiration of regulatory or patent exclusivities.

RESPONSE TO TOPIC NO. 24: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "generic erosion analysis," "sales," "expiration," and "exclusivities."

J&J further objects to this Topic as overbroad and overly burdensome to the extent it contains no temporal or date limitation, and calls for information, documents, or things generated for information before J&J's acquisition of Cougar Biotechnology, Inc. or after September 2, 2014—the date the '438 Patent issued. J&J also objects to this Topic to the extent that it seeks information that is not within J&J's possession, custody, or control. J&J also objects to this Topic

to the extent it is cumulative to, or duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Discovery Requests Nos. 22 and 25.

J&J further objects to the disclosure of commercial, marketing, advertising, regulatory, and other information to the extent it concerns countries other than the United States as overbroad, unduly burdensome, and disproportionate to the needs of this case because it seeks information with no relevance to any disputed matter of law or fact in this case.

J&J also objects to this Topic to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J objects to this Topic to the extent it seeks information subject to the rights of third parties, including obligations of confidentiality between any J&J and a third party.

J&J also object to this Topic as prematurely seeking expert discovery, and as seeking legal conclusions.

Subject to and without waiver of these Specific Objections and the General Objections above, J&J will produce one or more witnesses to testify generally regarding the anticipated timing of market entry of Generic Zytiga and the impact of that entry on Zytiga's sales and market share to the extent that responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.

TOPIC NO. 25: The negotiation and terms of any settlement with generic competitors sued for patent infringement relating to Zytiga.

RESPONSE TO TOPIC NO. 25: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "negotiation," "terms," and "settlement."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate

to the needs of this case to the extent it contains no temporal or date limitation.

J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or control, information that is publicly available, or information that is already in Relator's possession, custody, or control. J&J further objects to this Topic as cumulative to, and duplicative of, other discovery or information that has already been provided to Relator, specifically in response to Relator's Request for Production No. 51.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J further objects to this Topic to the extent it seeks information subject to the rights of third parties, including obligations of confidentiality between J&J and any third party.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because the Topic has no relevance to any disputed matter of law or fact in this case.

J&J will not produce a witness in response to this Topic.

TOPIC NO. 26: The negotiation and terms of any exclusive pharmacy agreements that was intended to, or had the effect of, maintaining or protecting Zytiga's market share against generic competition.

RESPONSE TO TOPIC NO. 26: J&J objects to this Topic as indefinite, vague, ambiguous, overbroad, unduly burdensome, seeking information that is not proportional to the needs of the case, and failing to describe with reasonable particularity the matters for examination, for example, in its use of the undefined terms "negotiation," "exclusive pharmacy agreements," and "protecting."

J&J further objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case to the extent it contains no temporal or date limitation. J&J further objects to this Topic to the extent it seeks information that is not within J&J's possession, custody, or

control, information that is publicly available, or information that is already in Relator's possession, custody, or control.

J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, and/or any other applicable privilege or protection. J&J further objects to this Topic to the extent it seeks information subject to the rights of third parties, including obligations of confidentiality between J&J and any third party.

J&J also objects to this Topic as overbroad, unduly burdensome, and disproportionate to the needs of this case because the Topic has no relevance to any disputed matter of law or fact in this case.

J&J will not produce a witness in response to this Topic.

Dated: March 2, 2024

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA; STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA, *ex rel.* ZACHARY SILBERSHER, Plaintiffs, v. JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, JOHNSON & JOHNSON, and BTG INTERNATIONAL LIMITED, Defendants.	Civil Action No. 19-12107 (MEF) (ESK) Hon. Michael E. Farbiarz, U.S.D.J. **DEFENDANTS' RESPONSES & OBJECTIONS TO RELATOR'S SIXTH REQUESTS FOR PRODUCTION**

DEFENDANTS' RESPONSES & OBJECTIONS TO RELATOR'S SIXTH REQUESTS FOR PRODUCTION

Pursuant to Federal Rules of Civil Procedure 26 and 34, Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson (collectively, "J&J"), by its counsel, hereby respond and object to Relator's Sixth Set of Requests for Production ("Requests").

PRELIMINARY STATEMENT

J&J's responses and objections to these Requests (collectively, "Responses") are based upon its good faith interpretation of the Requests. Nothing contained in these Responses shall be construed as a waiver of the attorney-client privilege, work-product protection, or any other protection or privilege. To the extent that any protected documents or information are inadvertently produced in response to these Requests, the production of such documents or information shall not constitute a waiver of any right to assert the applicability of any privilege or immunity to the documents or information, and any such documents or information shall be returned to J&J's counsel immediately upon discovery thereof.

In furnishing these Responses and identifying or producing information in response to the Requests, J&J does not admit or concede the authenticity, relevance, materiality, or admissibility into evidence of any alleged facts or information referenced in any Request, information included in J&J's Responses, or documents or information produced in response to the Requests. All objections to the use, at trial or otherwise, of any Response or any document disclosed as part of J&J's Responses, are hereby expressly reserved.

By responding to these Requests, J&J does not adopt any of the characterizations made by Relator in any of his Requests concerning the documents or things Relator is seeking or facts alleged and/or in dispute. J&J reserves the right to revise, correct, supplement, or clarify any of these Responses as appropriate pursuant to Rule 26(e)(1). J&J does not make a representation that any particular responsive documents exist or are in J&J's possession.

OBJECTIONS TO RELATOR'S DEFINITIONS AND INSTRUCTIONS

1. J&J objects to the definitions of "Defendant"; "Defendants"; "you"; "your"; and "yours" as vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity. J&J will interpret the aforementioned terms to include Defendants Janssen Biotech,

Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson, including the foregoing's employees and officers acting on their behalf.

2. J&J objects to Relator's Instructions to the extent that they attempt to impose obligations on J&J different from or in addition to those required by the Stipulated Amended Discovery Confidentiality Order ("Protective Order") (Dkt. 175). In responding to these Requests, J&J will comply with the Protective Order. Any productions made in response to these Requests are subject to the Protective Order or any amended versions of such order subsequently entered by the Court.

3. J&J objects to the Requests that call for documents that contain attorney work product, attorney opinion(s), and/or attorney-client communications. Such Requests seek documents that are exempt from discovery and protected from disclosure pursuant to the attorney-client privilege, the attorney work product doctrine, confidentiality agreements, or any other applicable privilege, doctrine, or protection. J&J will withhold documents on this basis, and it will identify such withheld documents in a manner as agreed by the parties.

4. J&J objects to the Requests as overly broad, unduly burdensome, disproportionate to the needs of this case, and duplicative, particularly given that many of the Requests merely repeat or seek to define Relator's prior Requests.

5. J&J objects to Relator's request that J&J produce documents responsive to the Requests within 30 days. If required, J&J will produce documents in response to certain of these Requests on a rolling basis following conclusion of any meet and confer.

RESPONSES AND OBJECTIONS TO RELATOR'S REQUESTS

REQUEST NO. 88: All documents related to any agreements between two or more of the Defendants to provide indemnity, cover costs, or reimburse for any liabilities related to this action.

RESPONSE TO REQUEST NO. 88: J&J objects to this Request because it is overly broad and unduly burdensome as it requests "all" documents. J&J also objects to this Request as unduly burdensome insofar as it is duplicative of Request No. 40. J&J incorporates its objections to that Request herein. J&J further objects to this Request as unduly burdensome because it seeks highly confidential documents, and documents with no relevance to any disputed matter of law or fact in this case. J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, or other applicable privileges and protections, including the joint defense privilege. J&J further objects to this Request to the extent that it seeks information or documents the production of which without appropriate safeguards would violate confidentiality agreements, arrangements, or understandings between or among J&J and other persons; the confidentiality of settlement discussions or agreements; or court orders.

J&J will not search for or produce documents in response to this Request.

REQUEST NO. 89: Documents concerning any contracts, agreements, or licenses between and among Defendants and affiliates of Defendants related to the development, research, manufacturing, sale, marketing, and distribution of Zytiga (including, without limitation, any rights to the '213 Patent and the '438 Patent).

RESPONSE TO REQUEST NO. 89: J&J objects to this Request as overly broad and unduly burdensome, particularly insofar as it is duplicative of Relator's prior Request No. 53. J&J incorporates its objections to that Request herein. J&J further objects to this Request as unduly burdensome on the ground that it seeks highly confidential documents, and documents with no relevance to any disputed matter of law or fact in this case. J&J further objects to this Request to

the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, or other applicable privileges and protections. J&J also objects to the term "affiliates" as undefined, vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity. J&J further objects to this Request insofar as it seeks information outside of J&J's possession, custody, or control. J&J is responding on its behalf only.

Subject to and without waiver of the foregoing objections, J&J agrees to meet and confer with Relator regarding this Request. J&J also refers Relator to documents previously produced at ZYTIGA_LIT_04832317; ZYTIGA_LIT_04940425; ZYTIGA_LIT_04945525; ZYTIGA_LIT_05398848; ZYTIGA_LIT_05408336; ZYTIGA_LIT_05408348; ZYTIGA_LIT_05434082; ZYTIGA_LIT_05734569 – ZYTIGA_LIT_05734599; and ZYTIGA_BTG0001159 as responsive to this Request.

REQUEST NO. 90: Documents sufficient to show the roles, rights, and responsibilities of J&J relating to the research, development, manufacture, marketing, or sale of Zytiga, including, without limitation, J&J's oversight, management, or control of any of the foregoing activities related to Zytiga.

RESPONSE TO REQUEST NO. 90: J&J objects to this Request as overly broad and unduly burdensome insofar as it is duplicative of many of Relator's other discovery requests, including Interrogatory Nos. 16 and 23 and Request for Admission Nos. 1–9. J&J further objects to this Request as unduly burdensome because it seeks highly confidential documents, and documents with no relevance to any disputed matter of law or fact in this case. J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, or other applicable privileges and protections, including the joint defense privilege. J&J also objects to the terms "roles," "rights," "responsibilities," "research," "development," "manufacture," "marketing," "sale," "oversight," "management," and "control"

as undefined, vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity.

Subject to and without waiver of the foregoing objections, J&J agrees to meet and confer with Relator regarding this Request.

REQUEST NO. 91: Documents sufficient to show the roles, rights, and responsibilities of Janssen Biotech relating to the research, development, manufacture, marketing, or sale of Zytiga, including, without limitation, Janssen Biotech's oversight, management, or control of any of the foregoing activities related to Zytiga.

RESPONSE TO REQUEST NO. 91: J&J objects to this Request as overly broad and unduly burdensome insofar as it is duplicative of Relator's other discovery requests, including Interrogatory Nos. 16 and 23 and Request for Admission Nos. 1–9. J&J further objects to this Request as unduly burdensome because it seeks highly confidential documents, and documents with no relevance to any disputed matter of law or fact in this case. J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, or other applicable privileges and protections, including the joint defense privilege. J&J also objects to the terms "roles," "rights," "responsibilities," "research," "development," "manufacture," "marketing," "sale," "oversight," "management," and "control" as undefined, vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity.

Subject to and without waiver of the foregoing objections, J&J agrees to meet and confer with Relator regarding this Request.

REQUEST NO. 92: Documents sufficient to show the roles, rights, and responsibilities of Janssen Oncology relating to the research, development, manufacture, marketing, or sale of Zytiga, including, without limitation, Janssen Oncology's oversight, management, or control of any of the foregoing activities related to Zytiga.

RESPONSE TO REQUEST NO. 92: J&J objects to this Request as overly broad and unduly burdensome insofar as it is duplicative of Relator's other discovery requests, including

Interrogatory Nos. 16 and 23 and Request for Admission Nos. 1–9. J&J further objects to this Request as unduly burdensome because it seeks highly confidential documents, and documents with no relevance to any disputed matter of law or fact in this case. J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, or other applicable privileges and protections, including the joint defense privilege. J&J also objects to the terms "roles," "rights," "responsibilities," "research," "development," "manufacture," "marketing," "sale," "oversight," "management," and "control" as undefined, vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity.

Subject to and without waiver of the foregoing objections, J&J agrees to meet and confer with Relator regarding this Request.

REQUEST NO. 93: Documents sufficient to show the roles, rights, and responsibilities of Janssen R&D relating to the research, development, manufacture, marketing, or sale of Zytiga, including, without limitation, Janssen R&D's oversight, management, or control of any of the foregoing activities related to Zytiga.

RESPONSE TO REQUEST NO. 93: J&J objects to this Request as overly broad and unduly burdensome insofar as it is duplicative of Relator's other discovery requests, including Interrogatory Nos. 16 and 23 and Request for Admission Nos. 1–9. J&J further objects to this Request as unduly burdensome because it seeks highly confidential documents, and documents with no relevance to any disputed matter of law or fact in this case. J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, or other applicable privileges and protections, including the joint defense privilege. J&J also objects to the terms "roles," "rights," "responsibilities," "research," "development," "manufacture," "marketing," "sale," "oversight," "management," and "control"

as undefined, vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity.

Subject to and without waiver of the foregoing objections, J&J agrees to meet and confer with Relator regarding this Request.

REQUEST NO. 94: Transactional details of the sale of Zytiga by each Defendant entity or their affiliates from 2011 to the present time, including, without limitation, sales to Medicare Plan D sponsors, the Department of Veterans Affairs, the Department of Health & Human Services (including the Centers for Medicare & Medicaid Services), and Zytiga Specialty Pharmacies for units intended for Government purchase or payment. Without limiting the foregoing, responsive documents include electronic records or spreadsheets showing sales of Zytiga including: (a) the National Drug Code (NDC) of the product sold; (b) the date of sale; (c) the number of units sold; (d) the price for each unit sold; (e) the total amount of sales; (f) the dosage, form, and strength of the product; (g) the purchaser; and (h) the purchaser's address or location.

RESPONSE TO REQUEST NO. 94: J&J objects to this Request as overly broad and unduly burdensome, particularly insofar as it is duplicative of several of Relator's prior Requests, specifically Request Nos. 32, 35, and 36. J&J incorporates its objections to those Requests herein. J&J also objects to this Request as overly broad and unduly burdensome because it seeks highly confidential documents. The Request is also overly broad and unduly burdensome because it seeks documents with no relevance to any disputed matter of law or fact in this case, particularly insofar as it requests details regarding sales of Zytiga from 2011 to present, which includes multiple years in which the disputed Patent was not in effect. J&J further objects to the term "affiliates" and phrase "intended for Government purchase or payment" as undefined, vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity. J&J further objects to this Request insofar as it seeks information outside of J&J's possession, custody, or control. J&J is responding on its behalf only.

Subject to and without waiver of the foregoing objections, J&J refers Relator to the documents previously produced at

ZYTIGA_LIT_05587250; ZYTIGA_LIT_05587251; ZYTIGA_LIT_05587252; ZYTIGA_LIT_05587253; ZYTIGA_LIT_05597118 – ZYTIGA_LIT_05597122, which were produced to Relator on June 9, 2023, and June 24, 2023, as responsive to this Request. J&J will not search for or produce additional documents or data in response to this Request.

REQUEST NO. 95: Defendants' agreements with Medicare Plan D sponsors, the Department of Veterans Affairs, and the Department of Health & Human Services (including the Centers for Medicare & Medicaid Services) for Zytiga from 2011 to the present time.

RESPONSE TO REQUEST NO. 95: J&J objects to this Request as overly broad and unduly burdensome, particularly insofar as it is duplicative of Relator's prior Request No. 31. J&J incorporates its objections to that Request herein. J&J also objects to this Request as overly broad and unduly burdensome because it seeks highly confidential documents. The Request is also overly broad and unduly burdensome because it seeks documents with no relevance to any disputed matter of law or fact in this case, particularly insofar as it requests agreements from 2011 to the present that were not operative while the disputed patent was in effect.

Subject to and without waiver of the foregoing objections, J&J refers Relator to documents previously produced at ZYTIGA_LIT_05415170 – ZYTIGA_LIT_0541802, which were produced to Relator on November 11, 2022, as responsive to this Request. J&J will not search for or produce additional documents in response to this Request.

REQUEST NO. 96: Transactional details of any rebates or similar reimbursements paid by each Defendant and their affiliates to the Department of Veterans Affairs and the Department of Health & Human Services (including the Centers for Medicare & Medicaid Services) for Zytiga from 2011 to the present time, including, without limitation, the corresponding National Drug Code (NDC); date of sale; number of units sold; dosage, form and strength; the purchaser; the purchaser's address or location, and sufficient identifying information to link the payment of any such rebate or similar reimbursement to a claim for payment from the government.

RESPONSE TO REQUEST NO. 96: J&J objects to this Request as overly broad and unduly burdensome, particularly insofar as it is duplicative of several of Relator's prior Requests,

specifically Request Nos. 32, 35, and 36. J&J incorporates its objections to those Requests herein. The Request is also overly broad and unduly burdensome because it seeks documents with no relevance to any disputed matter of law or fact in this case, particularly insofar as it requests details regarding sales of Zytiga from 2011 to present, which includes multiple years in which the disputed Patent was not in effect. J&J further objects to the terms "affiliates" and "similar reimbursements" as undefined, vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity. J&J further objects to this Request insofar as it seeks information outside of J&J's possession, custody, or control. J&J is responding on its behalf only.

Subject to and without waiver of the foregoing objections, J&J refers Relator to the documents previously produced at ZYTIGA_LIT_05587250; ZYTIGA_LIT_05587251; ZYTIGA_LIT_05587252; ZYTIGA_LIT_05587253; ZYTIGA_LIT_05597118 – ZYTIGA_LIT_05597122, which were produced to Relator on June 9, 2023, and June 24, 2023, as responsive to this Request. J&J will not search for or produce additional documents or data in response to this Request.

REQUEST NO. 97: Documents sufficient to show Defendants' prices, including rebates or similar reimbursements, for Zytiga to any government purchaser or payor for Zytiga from 2011 to the present time, including, without limitation, the setting of prices, and the calculation of rebates or similar reimbursements.

RESPONSE TO REQUEST NO. 97: J&J objects to this Request as overly broad and unduly burdensome, particularly insofar as it is duplicative of several of Relator's prior Requests, specifically Request Nos. 32, 35, and 36. J&J incorporates its objections to those Requests herein. J&J also objects to this Request as overly broad and unduly burdensome because it seeks highly confidential documents. The Request is also overly broad and unduly burdensome because it seeks documents with no relevance to any disputed matter of law or fact in this case, particularly insofar as it requests details regarding sales of Zytiga from 2011 to present, which includes multiple years

in which the disputed Patent was not in effect. J&J further objects to the term "similar reimbursements" as undefined, vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity.

Subject to and without waiver of the foregoing objections, J&J refers Relator to the documents previously produced at ZYTIGA_LIT_05587250; ZYTIGA_LIT_05587251; ZYTIGA_LIT_05587252; ZYTIGA_LIT_05587253; ZYTIGA_LIT_05597118 - ZYTIGA_LIT_05597122, which were produced to Relator on June 9, 2023, and June 24, 2023, as responsive to this Request. J&J will not search for or produce additional documents in response to this Request.

REQUEST NO. 98: Documents sufficient to show the nature, constitution, authority, and purpose of corporate groups or committees commonly used by J&J-related entities for the research, development, manufacture, marketing, or sale of pharmaceutical drugs such as Zytiga, including groups such as the Global Commercial Team and the Compound Development Team.

RESPONSE TO REQUEST NO. 98: J&J objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, or other applicable privileges and protections. J&J also objects to the terms "nature," "constitution," "authority," "purpose," "J&J-related entities," "research," "development," "manufacture," "marketing," and "sale," as undefined, vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity.

Subject to and without waiver of the foregoing objections, J&J refers Relator to the documents previously produced at ZYTIGA_LIT_06237604 – ZYTIGA_LIT_06238858 and ZYTIGA_LIT_06238916 – ZYTIGA_LIT_06241458, which were produced to Relator on January 19, 2024, and January 30, 2024, as responsive to this Request. J&J will not search for or produce additional documents in response to this Request.

REQUEST NO. 99: Documents concerning the appointment or inclusion of specific personnel to be part of any J&J-related group or committee related to Zytiga, including the Global Commercial Team and the Compound Development Team.

RESPONSE TO REQUEST NO. 99: J&J objects to this Request as overly broad and unduly burdensome because it seeks highly confidential documents, and documents with no relevance to any disputed matter of law or fact in this case. J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, or other applicable privileges and protections.

Subject to and without waiver of the foregoing objections, J&J agrees to meet and confer with Relator regarding this Request. J&J also refers Relator to the documents previously produced at ZYTIGA_LIT_06237604 – ZYTIGA_LIT_06238858 and ZYTIGA_LIT_06238916 – ZYTIGA_LIT_06241458, which were produced to Relator on January 19, 2024, and January 30, 2024, as responsive to this Request.

REQUEST NO. 100:Documents sufficient to show the valuation Defendants assigned to the '440 Application in connection with the acquisition of Cougar Biotechnology, Inc.

RESPONSE TO REQUEST NO. 100: J&J objects to this request as unduly burdensome because it seeks highly confidential documents, and documents with no relevance to any disputed matter of law or fact in this case. J&J also objects to this Request to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, or other applicable privileges and protections. J&J further objects to the terms "assigned" and "in connection with" as undefined, vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity.

Subject to and without waiver of the foregoing objections, J&J agrees to meet and confer with Relator regarding this Request.

Dated: March 15, 2024

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA; STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA, *ex rel*. ZACHARY SILBERSHER, Plaintiffs, v. JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, JOHNSON & JOHNSON, and BTG INTERNATIONAL LIMITED, Defendants.	Civil Action No. 19-12107 (MEF) (ESK) Hon. Michael E. Farbiarz, U.S.D.J. **DEFENDANTS' RESPONSES TO RELATOR'S FIRST SET OF REQUESTS FOR ADMISSIONS.**

Pursuant to Federal Rule of Civil Procedure 36, Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson hereby respond to the First Set of Requests for Admissions propounded by Relator Zachary Silbersher.

PRELIMINARY STATEMENT

Pursuant to Rules 26 and 36 of the Federal Rules of Civil Procedure, Defendants Janssen Biotech, Inc. ("Janssen Biotech"), Janssen Oncology, Inc. ("Janssen Oncology"), Janssen

Research & Development, LLC ("Janssen R&D"), and Johnson & Johnson (collectively, "Defendants"), by and through their undersigned counsel, hereby provide their responses and objections to Plaintiff-Relator's First Set of Requests for Admissions (Nos. 1-25).

Defendants do not waive any objection to the use of any information contained in their responses below for any purpose in this or any other proceeding, and expressly reserve the right to object to the use of such information on any appropriate ground.

Defendants reserve all rights to amend and supplement these objections and responses to the fullest extent allowed by the applicable federal and local rules, the court-ordered case schedule, and any agreement of the parties.

For avoidance of doubt, all Requests are denied except as explicitly admitted in the numbered responses below.

OBJECTIONS TO RELATOR'S DEFINITIONS AND INSTRUCTIONS

Defendants object to the definitions of "Defendant"; "Defendants"; "you"; "your"; and "yours" as vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity. Defendants will interpret the aforementioned terms to include Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson, including the foregoing's employees and officers acting on their behalf, only.

Defendants object to the definitions of "Actavis," "Agreements," "Amerigen," "Amneal," "Apotex," "Arab Pharma," "Authorized Generic," "Citron," "Commercial Success Argument," "Dr. Reddy's," "Generic Zytiga ANDA Filer," "Government," "Hetero," "Hikma," "Internal Communications," "Inter Partes Reviews," "Lupin," "Mylan," "MSN Laboratories," "Par," "Plaintiff State," "Proposed," "Sun," "Teva," "West-Ward," "Wockhardt," and "Zytiga Specialty Pharmacy" as those terms are not used in the Requests.

Defendants object to the definition of "Janssen" as vague, ambiguous, overbroad, unduly

burdensome, and not described with reasonable particularity. Defendants will interpret the aforementioned "Janssen" to include Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson.

Defendants object to the Requests that call for information that is or contains attorney work product, attorney opinion(s), and/or attorney-client communications. Such Requests seek information that is exempt from discovery and protected from disclosure pursuant to the attorney-client privilege, the attorney-work product doctrine, confidentiality agreements, or any other applicable privilege, doctrine, or protection. No information subject to such privilege, doctrine, protection, or immunity will be provided.

Defendants object to each of the Definitions and Instructions to the extent they render each Request vague and/or unduly burdensome. Defendants will give the words in each Request their ordinary language meaning, and will provide answers in accordance with the applicable rules and orders.

Defendants object to each Request and to each Definition and Instruction to the extent they characterize disputed facts or imply any particular legal conclusion. Plaintiffs do not concede the truth or accuracy of any statements made in Relator's Requests, Definitions, and Instructions.

Defendants object to each Request to the extent its purports to require Defendants to reach a legal conclusion in order to respond.

RESPONSES AND OBJECTIONS TO RELATOR'S REQUESTS FOR ADMISSION

REQUEST NO. 1

Admit that during all relevant time periods, Johnson & Johnson exercised control over the sale of Zytiga.

RESPONSE TO REQUEST NO. 1

Defendants object to the term "exercised control" as undefined, vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity.

Subject to the aforementioned objections, Defendants admit that Johnson & Johnson sold Zytiga, including by and through its subsidiaries, for use in combination with prednisone in the United States from April 28, 2011 through the present time. Defendants otherwise cannot admit or deny this Request, including because the meaning of the term "exercised control" has not been defined and is vague and ambiguous. Defendants are willing to meet and confer with Relator to understand the information sought by this Request.

REQUEST NO. 2

Admit that during all relevant time periods, Janssen Biotech exercised control over the sale of Zytiga.

RESPONSE TO REQUEST NO. 2

Defendants object to the term "exercised control" as undefined, vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity.

Defendants refer Relator to their response to Request No. 1. Defendants state that they otherwise cannot admit or deny this Request, including because the meaning of the term "exercised control" has not been defined and is vague and ambiguous. Defendants are willing to meet and confer with Relator to understand the information sought by this Request.

REQUEST NO. 3

Admit that during all relevant time periods, Janssen Oncology exercised control over the sale of Zytiga.

RESPONSE TO REQUEST NO. 3

Defendants object to the term "exercised control" as undefined, vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity.

Defendants refer Relator to their response to Request No. 1. Defendants state that they otherwise cannot admit or deny this Request, including because the meaning of the term "exercised control" has not been defined and is vague and ambiguous. Defendants are willing to meet and confer with Relator to understand the information sought by this Request.

REQUEST NO. 4

Admit that during all relevant time periods, Janssen R&D exercised control over the sale of Zytiga.

RESPONSE TO REQUEST NO. 4

Defendants object to the term "exercised control" as undefined, vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity.

Defendants refer Relator to their response to Request No. 1. Defendants state that they otherwise cannot admit or deny this Request, including because the meaning of the term "exercised control" has not been defined and is vague and ambiguous. Defendants are willing to meet and confer with Relator to understand the information sought by this Request.

REQUEST NO. 5

Admit that Johnson & Johnson exercised control over prosecution of the '340 Application.

RESPONSE TO REQUEST NO. 5

Defendants object to the term "exercised control" as undefined, vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity.

Subject to the aforementioned objections, Defendants admit that Johnson & Johnson prosecuted the '340 Application, including by and through its employees and subsidiaries. Defendants otherwise cannot admit or deny this Request, including because the meaning of the term "exercised control" has not been defined and is vague and ambiguous. Defendants are willing to meet and confer with Relator to understand the information sought by this Request.

REQUEST NO. 6

Admit that all Defendants were and are real parties in interest in the '438 Patent.

RESPONSE TO REQUEST NO. 6

Defendants object to the term "real parties in interest" as undefined, vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity.

Subject to the aforementioned objections, Defendants admit that Janssen Oncology, Inc. was the assignee listed on the '438 Patent. Defendants otherwise cannot admit or deny this Request, including because the meaning of the term "real parties in interest" has not been defined and is vague and ambiguous. Defendants are willing to meet and confer with Relator to understand the information sought by this Request.

REQUEST NO. 7

Admit that Johnson & Johnson, Janssen Biotech, Janssen Oncology and Janssen Research & Development collectively sell Zytiga pursuant to NDA No. 202379.

RESPONSE TO REQUEST NO. 7

Defendants object to the term "collectively sell" as undefined, vague, ambiguous,

overbroad, unduly burdensome, and not described with reasonable particularity.

Subject to the aforementioned objections, Defendants admit that Johnson & Johnson sold Zytiga, including by and through its subsidiaries, for use in combination with prednisone in the United States pursuant to NDA No. 202379 from April 28, 2011 through the present time. Defendants otherwise cannot admit or deny this Request, including because the meaning of the term "collectively sell" has not been defined and is vague and ambiguous. Defendants are willing to meet and confer with Relator to understand the information sought by this Request.

REQUEST NO. 8

Admit that all Defendants were and are real parties in interest in the '438 Patent.

RESPONSE TO REQUEST NO. 8

Defendants object that this Request is identical to and duplicative of Request No. 6. Defendants refer Relator to their Response to that Request.

REQUEST NO. 9

Admit that during all relevant time periods, Johnson & Johnson arranged for the sale of Zytiga through its wholly owned subsidiaries, including the Janssen entities and their affiliates.

RESPONSE TO REQUEST NO. 9

Defendants object to the terms "Janssen entities and their affiliates" and "arranged for the sale" as undefined, vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity. Defendants will construe the term "Janssen entities and their affiliates" to refer to Defendants only.

Subject to the aforementioned objections, Defendants admit that Johnson & Johnson sold Zytiga, including by and through its subsidiaries, for use in combination with prednisone in the United States from April 28, 2011 through the present time. Defendants otherwise cannot admit

or deny this Request, including because the meaning of the terms "Janssen entities and their affiliates" and "arranged for the sale" have not been defined and are vague and ambiguous. Defendants are willing to meet and confer with Relator to understand the information sought by this Request.

REQUEST NO. 10

Admit that Johnson & Johnson directed, managed, and controlled the Patent Infringement Actions to exclude generic competitors from entering the market prior to the expiration of the '438 Patent.

RESPONSE TO REQUEST NO. 10

Defendants object to the terms "directed," "managed," and "controlled" as undefined, vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity. Defendants object to this Request to the extent it seeks privileged information and the admission of a legal conclusion.

Subject to the aforementioned objections, Defendants deny this Request.

REQUEST NO. 11

Admit that during the prosecution of the '438 Patent, each Defendant knew that prednisone coadministration was a material weakness of Zytiga against competing treatments, such as XTANDI, and therefore posed a substantial threat or potential impediment to Zytiga's commercial success.

RESPONSE TO REQUEST NO. 11

Defendants object to the terms "material weakness," "competing treatments," "substantial threat," and "potential impediment" as vague, ambiguous, overbroad, unduly burdensome, not described with reasonable particularity, and undefined. Defendants object to this Request to the

extent it seeks admission of a legal conclusion. Defendants object to this Request because it calls for Defendants to assume facts and conclusions that are not established by the record.

Subject to the aforementioned objections, Defendants deny this Request.

REQUEST NO. 12

Admit that during the prosecution of the '438 Patent, each Defendant knew that Zytiga held a material competitive advantage against competitors, including, without limitation, XTANDI, because it had or was expected to have FDA approval before those competing treatments.

RESPONSE TO REQUEST NO. 12

Defendants object to the terms "material competitive advantage" and "competing treatments" as vague, ambiguous, overbroad, unduly burdensome, not described with reasonable particularity, and undefined. Defendants object to this Request to the extent it seeks admission of a legal conclusion. Defendants object to this Request because it calls for Defendants to assume facts and conclusions that are not established by the record.

Subject to the aforementioned objections, Defendants deny this Request.

REQUEST NO. 13

Admit that during the prosecution of the '438 Patent, each Defendant knew that Zytiga held a material competitive advantage against competitors, because it had a first mover advantage against competing treatments.

RESPONSE TO REQUEST NO. 13

Defendants object to the terms "material competitive advantage," "first mover advantage," and "competing treatments" as vague, ambiguous, overbroad, unduly burdensome, not described with reasonable particularity, and undefined. Defendants object to this Request to the extent it seeks admission of a legal conclusion. Defendants object to this Request because it calls for

Defendants to assume facts and conclusions that are not established by the record.

Subject to the aforementioned objections, Defendants deny this Request.

REQUEST NO. 14

Admit that during the prosecution of the '438 Patent, each Defendant knew that Zytiga held a material competitive advantage against competitors based on each of the factors listed in paragraphs 84 and 87 of the Complaint.

RESPONSE TO REQUEST NO. 14

Defendants object to the terms "material competitive advantage," "competitors," and "factors" as vague, ambiguous, overbroad, unduly burdensome, not described with reasonable particularity, and undefined. Defendants object to this Request to the extent it seeks admission of a legal conclusion. Defendants object to this Request because it calls for Defendants to assume facts and conclusions that are not established by the record.

Subject to the aforementioned objections, Defendants deny this Request.

REQUEST NO. 15

Admit that during the prosecution of the '438 Patent, each Defendant knew that the majority of Zytiga's market share would be lost once the '213 patent expired, unless Defendants obtained approval of the '438 patent or other patent granting market exclusivity against generic competitors.

RESPONSE TO REQUEST NO. 15

Defendants object to the terms "material competitive advantage," "competitors," and "factors" as vague, ambiguous, overbroad, unduly burdensome, not described with reasonable particularity, and undefined. Defendants object to this Request to the extent it seeks privileged information and the admission of a legal conclusion.

Subject to the aforementioned objections, Defendants deny this Request.

REQUEST NO. 16

Admit that Defendants did not disclose to the Patent Office that Defendants enjoyed an exclusive license to the '213 Patent.

RESPONSE TO REQUEST NO. 16

Defendants object to the term "exclusive license" as vague, ambiguous, overbroad, unduly burdensome, not described with reasonable particularity, and undefined. Defendants object to this Request to the extent it seeks admission of a legal conclusion. Defendants object to this Request because it calls for Defendants to assume facts and conclusions that are not established by the record.

Subject to the aforementioned objections, Defendants deny this Request.

REQUEST NO. 17

Admit that Defendants did not disclose to the Patent Office that prednisone coadministration was a material weakness of Zytiga against competing treatments, such as XTANDI, and therefore posed a substantial threat or potential impediment to Zytiga's commercial success.

RESPONSE TO REQUEST NO. 17

Defendants object to the terms "material weakness," "competing treatments," "substantial threat," and "potential impediment" as vague, ambiguous, overbroad, unduly burdensome, not described with reasonable particularity, and undefined. Defendants object to this Request to the extent it seeks admission of a legal conclusion. Defendants object to this Request because it calls for Defendants to assume facts and conclusions that are not established by the record.

Subject to the aforementioned objections, Defendants deny this Request.

REQUEST NO. 18

Admit that Defendants did not disclose to the Patent Office that Zytiga held a material competitive advantage against competitors, including, without limitation, XTANDI, because it had or was expected to have FDA approval before those competing treatments.

RESPONSE TO REQUEST NO. 18

Defendants object to the terms "material competitive advantage" and "competing treatments" as vague, ambiguous, overbroad, unduly burdensome, not described with reasonable particularity, and undefined. Defendants object to this Request to the extent it seeks admission of a legal conclusion. Defendants object to this Request because it calls for Defendants to assume facts and conclusions that are not established by the record.

Subject to the aforementioned objections, Defendants deny this Request.

REQUEST NO. 19

Admit that Defendants did not disclose to the Patent Office that Zytiga held a material competitive advantage against competitors, because it had a first mover advantage against competing treatments.

RESPONSE TO REQUEST NO. 19

Defendants object to the terms "material competitive advantage," "first mover advantage," and "competing treatments" as vague, ambiguous, overbroad, unduly burdensome, not described with reasonable particularity, and undefined. Defendants object to this Request to the extent it seeks admission of a legal conclusion. Defendants object to this Request because it calls for Defendants to assume facts and conclusions that are not established by the record.

Subject to the aforementioned objections, Defendants deny this Request.

REQUEST NO. 20

Admit that Defendants did not disclose to the Patent Office any of the alleged factors for Zytiga's commercial success set forth in paragraphs 84 and 87 of the Complaint.

RESPONSE TO REQUEST NO. 20

Defendants object to this request to the extent it seeks admission of a legal conclusion. Defendants object to this Request because it calls for Defendants to assume facts and conclusions that are not established by the record.

Subject to the aforementioned objections, Defendants deny this Request.

REQUEST NO. 21

Admit that the documents in the Bates ranges listed in **Exhibit A** are true and authentic copies of the genuine original documents.

RESPONSE TO REQUEST NO. 21

Defendants object to this Request as overly broad, unduly burdensome, and disproportionate to the needs of the case. Rule 36 contemplates that requests to admit the genuineness of a document must "describe[]" that document. *See* FRCP 36(a)(1)(B). Neither Request No. 21 nor Exhibit A describes a document. Defendants also object that Exhibit A lists 20,617 documents. Such an excessive volume of documents is not contemplated by Rule 36 and renders this Request unduly burdensome.

Subject to the forgoing objections, Defendants are unable to admit or deny this Request.

REQUEST NO. 22

Admit that the documents in the Bates ranges listed in **Exhibit A** were made at or near the time of the regularly conducted activity to which the documents pertain.

RESPONSE TO REQUEST NO. 22

Defendants object to this Request as overly broad, unduly burdensome, and disproportionate to the needs of the case. Rule 36 contemplates that requests to admit the genuineness of a document must "describe[]" that document. *See* FRCP 36(a)(1)(B). Neither Request No. 22 nor Exhibit A describes a document. Defendants also object that Exhibit A lists 20,617 documents. Such an excessive volume of documents is not contemplated by Rule 36 and renders this Request unduly burdensome.

Subject to the forgoing objections, Defendants are unable to admit or deny this Request.

REQUEST NO. 23

Admit that the documents in the Bates ranges listed in **Exhibit A** were prepared and kept by Defendants in the course of regularly conducted activity of a business, organization, occupation, or calling.

RESPONSE TO REQUEST NO. 23

Defendants object to this Request as overly broad, unduly burdensome, and disproportionate to the needs of the case. Rule 36 contemplates that requests to admit the genuineness of a document must "describe[]" that document. *See* FRCP 36(a)(1)(B). Neither Request No. 23 nor Exhibit A describes a document. Defendants also object that Exhibit A lists 20,617 documents. Such an excessive volume of documents is not contemplated by Rule 36 and renders this Request unduly burdensome.

Subject to the forgoing objections, Defendants are unable to admit or deny this Request.

REQUEST NO. 24

Admit that the documents in the Bates ranges listed in **Exhibit A** were made in the regular practice of the activity to which the documents pertain.

RESPONSE TO REQUEST NO. 24

Defendants object to this Request as overly broad, unduly burdensome, and disproportionate to the needs of the case. Rule 36 contemplates that requests to admit the genuineness of a document must "describe[]" that document. *See* FRCP 36(a)(1)(B). Neither Request No. 24 nor Exhibit A describes a document. Defendants also object that Exhibit A lists 20,617 documents. Such an excessive volume of documents is not contemplated by Rule 36 and renders this Request unduly burdensome.

Subject to the forgoing objections, Defendants are unable to admit or deny this Request.

REQUEST NO. 25

Admit that all foundational requirements for the admission of documents in the Bates ranges listed in **Exhibit A** have been satisfied.

RESPONSE TO REQUEST NO. 25

Defendants object to this Request as overly broad, unduly burdensome, and disproportionate to the needs of the case. Rule 36 contemplates that requests to admit the genuineness of a document must "describe[]" that document. *See* FRCP 36(a)(1)(B). Neither Request No. 25 nor Exhibit A describes a document. Defendants also object that Exhibit A lists 20,617 documents. Such an excessive volume of documents is not contemplated by Rule 36 and renders this Request unduly burdensome.

Subject to the forgoing objections, Defendants are unable to admit or deny this Request.

Dated: March 18, 2024

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA; STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA, *ex rel*. ZACHARY SILBERSHER, Plaintiffs, v. JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, JOHNSON & JOHNSON, and BTG INTERNATIONAL LIMITED, Defendants.	Civil Action No. 19-12107 (MEF) (ESK) Hon. Michael E. Farbiarz, U.S.D.J. **DEFENDANTS' RESPONSES TO RELATOR'S SECOND SET OF INTERROGATORIES.**

Pursuant to Federal Rule of Civil Procedure 33, Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson (collectively, "J&J") hereby respond to the Second Set of Interrogatories propounded by Relator Zachary Silbersher.

PRELIMINARY STATEMENT

J&J's responses and objections to these Interrogatories (collectively, "Responses") are based upon its good faith interpretation of the Interrogatories. Nothing contained in these Responses shall be construed as a waiver of the attorney-client privilege, work-product protection, or any other protection or privilege. To the extent that any such protected documents or information are inadvertently produced in response to these Interrogatories, the production of such documents or information shall not constitute a waiver of any right to assert the applicability of any privilege or immunity to the documents or information, and any such documents or information shall be returned to J&J's counsel immediately upon discovery thereof.

In furnishing these Responses and identifying or producing information in response to the Interrogatories, J&J does not admit or concede the authenticity, relevance, materiality, or admissibility into evidence of any alleged facts or information referenced in any Interrogatory, information included in J&J's Responses, or documents or information produced in response to the Interrogatories. All objections to the use, at trial or otherwise, of any Response or any document disclosed as part of J&J's Response, are hereby expressly reserved.

By responding to these Interrogatories, J&J does not adopt any of the characterizations made by Relator in any of his Interrogatories concerning the information, documents, or things Relator is seeking or facts alleged and/or in dispute. J&J reserves the right to revise, correct, supplement, or clarify any of these Responses and objections as appropriate pursuant to Rule 26(e)(1), including after J&J completes any document productions. Fact discovery is ongoing and expert discovery has not yet begun. J&J has not completed the investigation and discovery relating to this matter that may be necessary, and these Responses are based upon, and necessarily limited

by, information reasonably and presently available to J&J. J&J does not make a representation that any particular information or responsive documents exist or are in J&J's possession.

To the extent documents are produced pursuant to Rule 33(d), J&J will produce copies of documents or electronically stored information ("ESI").

For organizational purposes, J&J has used the interrogatory numbers identified by Relator. In so doing, J&J does not agree that each interrogatory designated by a single number constitutes a single interrogatory under Rule 33 of the Federal Rules of Civil Procedure.

OBJECTIONS TO RELATOR'S DEFINITIONS AND INSTRUCTIONS

J&J objects to the definitions of "Defendant"; "Defendants"; "you"; "your"; and "yours" as vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity. J&J will interpret the aforementioned terms to include Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson, including the foregoing's employees and officers acting on their behalf.

J&J objects to the definition of "Patent Applications" as that term is not used in the Interrogatories.

J&J objects to the definition of "Authorized Generic" as vague, ambiguous, overbroad, unduly burdensome, not described with reasonable particularity, and not used in the Interrogatories.

J&J objects to the definition of "Janssen" as vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity. J&J will interpret the aforementioned "Janssen" to include Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson.

J&J objects to the Interrogatories that call for information that is or contains attorney work product, attorney opinion(s), and/or attorney-client communications. Such Interrogatories seek

information that is exempt from discovery and protected from disclosure pursuant to the attorney-client privilege, the attorney-work product doctrine, confidentiality agreements, or any other applicable privilege, doctrine, or protection. No information subject to such privilege, doctrine, protection, or immunity will be provided.

J&J objects to the relevant time period because it is overly broad and unduly burdensome for the needs of this case. J&J agrees to meet and confer with Relator regarding an appropriate time period for specific Interrogatories as identified in its Responses below.

RESPONSES AND OBJECTIONS TO RELATOR'S INTERROGATORIES

RELATOR'S INTERROGATORY #16

Describe in detail the roles, rights, and responsibilities of each corporate entity that participated, during the relevant period, in the research, development, manufacture, marketing, or sale of Zytiga.

RESPONSE TO INTERROGATORY #16

J&J objects to this Interrogatory as unduly burdensome because it seeks highly confidential information, and information with no relevance to any disputed matter of law or fact in this case. J&J also objects to this Interrogatory to the extent that it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, or other applicable privileges and protections, including the joint defense privilege. J&J also objects to the terms "roles," "rights," "responsibilities," "research," "development," "corporate entity," "participated," "manufacture," "marketing," and "sale," as undefined, vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity. J&J further objects to this Request insofar as it seeks information outside of J&J's possession, custody, or control. J&J is responding on its behalf only.

J&J objects to this Interrogatory as multiple interrogatories.

Subject to the aforementioned objection, J&J responds as follows: Johnson & Johnson is a publicly traded company that has no parent, and which wholly owns numerous operating companies that operate worldwide. Those wholly-owned entities include Janssen Biotech, Inc., Janssen Oncology, Inc., and Janssen Research and Development, LLC, each of which has been named as a defendant in this action. The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company.

J&J is willing to meet and confer with Relator to understand the information sought by this Interrogatory. J&J reserves all rights to supplement the Response to this Interrogatory as discovery and other fact-finding continues.

RELATOR'S INTERROGATORY #17

For each of your responses to the Requests for Admission served with these Interrogatories that is not an unqualified admission, state all facts upon which you base your response.

RESPONSE TO INTERROGATORY #17

J&J objects to this Interrogatory because it is overly broad and unduly burdensome in that it requests "all" information for a given subject matter. J&J further objects to this Interrogatory as multiple interrogatories. "An interrogatory's subparts are to be counted as separate and discrete subparts 'if they are not logically or factually subsumed within and necessarily related to the primary question.'" *Carpenter v. Donegan*, 2012 WL 893472, at *2 (N.D.N.Y. Mar. 15, 2012) (quoting *Madison v. Nesmith*, 2008 WL 619171, at *3 (N.D.N.Y. Mar .3, 2008)). As applied here, courts generally recognize that "requests for admission deal with discrete or separate subjects." *Safeco of Am. v. Rawstron*, 181 F.R.D. 441, 446 (C.D. Cal. 1998). "Allowing service of an interrogatory which requests disclosure of all of the information on which the denials … were

based … essentially transforms each request for admission into an interrogatory." *Id.* at 445. This is improper because requests for admission are not, strictly speaking, a discovery device. *See* 8b Wright & Miller, Federal Practice and Procedure § 2252, at n.3 (3d. ed.). Yet that is precisely what this Interrogatory purports to do.

Because J&J makes denials or qualified admissions in response to 25 of Relator's Requests for Admission, none of which are "logically or factually subsumed" within one another, this Interrogatory constitutes 25 separate Interrogatories and is therefore improper under Rule 33(a) because it results in more than 25 Interrogatories being served on Defendants in this case.

RELATOR'S INTERROGATORY #18

For each Defendant entity and their affiliates, please state the amount of sales of Zytiga from 2011 to the present time to Medicare Plan D sponsors, the Department of Veterans Affairs, the Department of Health & Human Services (including the Centers for Medicare & Medicaid Services), and Zytiga Specialty Pharmacies for units intended for Government purchase or payment, including the following information: (a) the National Drug Code (NDC) of the product sold; (b) the date of sale; (c) the number of units sold; (d) the price for each unit sold; (e) the total amount of sales; (f) the dosage, form, and strength of the product; (g) the purchaser; and (h) the purchaser's address or location.

RESPONSE TO INTERROGATORY #18

J&J objects to this Interrogatory as overly broad and unduly burdensome because it seeks information with no relevance to any disputed matter of law or fact in this case, particularly insofar as it requests details regarding sales of Zytiga from 2011 to present, which includes multiple years in which the disputed Patent was not in effect. J&J further objects to the term "affiliates" and phrase "intended for Government purchase or payment" as undefined, vague, ambiguous,

overbroad, unduly burdensome, and not described with reasonable particularity. J&J further objects to this Request insofar as it seeks information outside of J&J's possession, custody, or control. J&J is responding on its behalf only.

Subject to and without waiver of the foregoing objections, J&J refers Relator to the documents previously produced at ZYTIGA_LIT_05587250; ZYTIGA_LIT_05587251; ZYTIGA_LIT_05587252; ZYTIGA_LIT_05587253; ZYTIGA_LIT_05597118 – ZYTIGA_LIT_05597122, which were produced to Relator on June 9, 2023, and June 24, 2023, as responsive to this Interrogatory.

J&J reserves all rights to supplement the Response to this Interrogatory as discovery and other fact-finding continues.

RELATOR'S INTERROGATORY #19

For each Defendant entity and their affiliates, please state the amount of rebates or similar reimbursements paid by each Defendant and their affiliates to the Department of Veterans Affairs and the Department of Health & Human Services (including the Centers for Medicare & Medicaid Services) for Zytiga for each month from 2011 to the present time, including, without limitation, the corresponding National Drug Code (NDC); date of sale; number of units sold; dosage, form and strength; the purchaser; the purchaser's address or location, the original price, and sufficient identifying information to link the payment of any such rebate or similar reimbursement to a claim for payment from the government.

RESPONSE TO INTERROGATORY #19

J&J objects to this Interrogatory as overly broad and unduly burdensome because it seeks information with no relevance to any disputed matter of law or fact in this case, particularly insofar as it requests details regarding sales of Zytiga from 2011 to present, which includes multiple years

in which the disputed Patent was not in effect. J&J further objects to the terms "affiliates" and "similar reimbursements" as undefined, vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity. J&J also objects to this Interrogatory insofar as it seeks information outside of J&J's possession, custody, or control. J&J is responding on its behalf only.

Subject to and without waiver of the foregoing objections, J&J refers Relator to the documents previously produced at ZYTIGA_LIT_05587250; ZYTIGA_LIT_05587251; ZYTIGA_LIT_05587252; ZYTIGA_LIT_05587253; ZYTIGA_LIT_05597118 – ZYTIGA_LIT_05597122, which were produced to Relator on June 9, 2023, and June 24, 2023, as responsive to this Interrogatory.

J&J reserves all rights to supplement the Response to this Interrogatory as discovery and other fact-finding continues.

RELATOR'S INTERROGATORY #20

If you currently believe there are any factors that provided Zytiga a competitive advantage against competing treatments that you did not know about or believe at the time that you submitted the Commercial Success Argument to the Patent Office when prosecuting the '438 Patent, please state all such factors and facts supporting them.

RESPONSE TO INTERROGATORY #20

J&J objects to this Interrogatory as duplicative of Interrogatory No. 6. J&J further objects to the terms "competitive advantage" and "competing treatments" as vague, ambiguous, overbroad, unduly burdensome, not described with reasonable particularity, and undefined. J&J further objects to this Interrogatory because it is overly broad and unduly burdensome in that it requests "all" and "any" information for a given subject matter. J&J also objects to this

Interrogatory as unduly burdensome on the ground that it seeks information with no relevance to any disputed matter of law or fact in this case. J&J objects to this Interrogatory to the extent it calls for a legal conclusion in order to either respond or to determine whether any information is responsive. J&J also objects to this Interrogatory to the extent it assumes facts and conclusions not established by the record. J&J further objects that this Interrogatory is premature and an improper contention request insofar as fact discovery is ongoing, expert discovery has not yet begun, Relator bears the burden of proof, and he has yet to satisfy his discovery obligations, which is necessary to permit J&J to identify facts and evidence in rebuttal. J&J objects that the response to this Interrogatory may be the subject of expert testimony.

Subject to and without waiver of the foregoing objections, J&J responds as follows:

J&J believes that there are no such factors. J&J also refers Relator to its Response to Interrogatory No. 6.

J&J reserves all rights to supplement the Response to this Interrogatory as discovery and other fact-finding continues.

RELATOR'S INTERROGATORY #21

If you believe that Defendants were not obligated or required to inform the Patent Office of any of the factors alleged to be responsible in part for the commercial success of Zytiga as set forth in Paragraphs 84 and 87 of the Complaint during the prosecution of the '438 patent, please state all the legal and factual bases for such belief or contention.

RESPONSE TO INTERROGATORY #21

J&J objects to this Interrogatory because it seeks material protected from disclosure by the attorney-client privilege, work-product doctrine, or other applicable privileges and protections. J&J further objects to this Interrogatory because it is overly broad and unduly burdensome in that

it requests "all" information for a given subject matter. J&J objects to this Interrogatory to the extent it calls for a legal conclusion in order to either respond or to determine whether any information is responsive. J&J also objects to this Interrogatory to the extent it assumes facts and conclusions not established by the record. J&J further objects that this Interrogatory is premature and an improper contention request insofar as fact discovery is ongoing, expert discovery has not yet begun, Relator bears the burden of proof, and he has yet to satisfy his discovery obligations, which is necessary to permit J&J to identify facts and evidence in rebuttal. J&J objects that the response to this Interrogatory may be the subject of expert testimony.

Subject to the aforementioned objections, J&J responds as follows:

J&J refers Relator to Defendants' Revised Response to Interrogatory 13, describing how J&J's submissions were consistent with their obligations to the USPTO in their prosecution of the '340 Application.

J&J reserves all rights to supplement the Response to this Interrogatory as discovery and other fact-finding continues.

RELATOR'S INTERROGATORY #22

If you believe that Defendants were not obligated or required to inform the Patent Office that prednisone coadministration was an impediment or a competitive disadvantage for the commercial success of Zytiga during prosecution of the '438 patent, please state all the legal and factual bases for such belief or contention.

RESPONSE TO INTERROGATORY #22

J&J objects to this Interrogatory because it is overly broad and unduly burdensome in that it requests "all" information for a given subject matter. J&J also objects to this Interrogatory to the extent it calls for a legal conclusion in order to either respond or to determine whether any

information is responsive. J&J objects to this Interrogatory to the extent it assumes facts and conclusions not established by the record. J&J further objects that this Interrogatory is premature and an improper contention request insofar as fact discovery is ongoing, expert discovery has not yet begun, Relator bears the burden of proof, and he has yet to satisfy his discovery obligations, which is necessary to permit J&J to identify facts and evidence in rebuttal. J&J also objects that the response to this Interrogatory may be the subject of expert testimony.

Subject to the aforementioned objections, J&J responds as follows:

J&J refers Relator to Defendants' Revised Response to Interrogatory 13, describing how J&J's submissions were consistent with their obligations to the USPTO in their prosecution of the '340 Application.

J&J reserves all rights to supplement the Response to this Interrogatory as discovery and other fact-finding continues.

RELATOR'S INTERROGATORY #23

Please describe the ownership, control, and corporate relationships between and among Defendants and their affiliates involved in the research, development, marketing, and sale of Zytiga, including, without limitation, how ownership in each entity is held and by which entity or entities.

RESPONSE TO INTERROGATORY #23

J&J objects to this Interrogatory as unduly burdensome because it seeks highly confidential information, and information with no relevance to any disputed matter of law or fact in this case. J&J also objects to the terms "ownership," "control," "corporate relationships," "affiliates," "research," "development," "marketing," and "sale," as undefined, vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity. J&J further objects to this

Interrogatory insofar as it seeks information outside of J&J's possession, custody, or control. J&J is responding on its behalf only.

Subject to and without waiver of the foregoing objections, J&J responds as follows:

Janssen Biotech, Inc., Janssen Oncology, Inc., and Janssen Research & Development, LLC are wholly owned subsidiaries of Johnson & Johnson. Johnson & Johnson is a publicly traded corporation that has no parent company.

RELATOR'S INTERROGATORY #24

If you contend that Defendants' obtaining the '438 Patent, listing the '438 Patent in the Orange Book, and asserting the '438 Patent against generic competitors in patent infringement actions did not delay generic entry, please state all the legal and factual bases for such belief or contention.

RESPONSE TO INTERROGATORY #24

J&J objects to this Interrogatory to the extent it calls for a legal conclusion in order to either respond or to determine whether any information is responsive. J&J also objects to this Interrogatory to the extent it assumes facts and conclusions not established by the record. J&J further objects that this Interrogatory is premature and an improper contention request insofar as fact discovery is ongoing, expert discovery has not yet begun, Relator bears the burden of proof, and he has yet to satisfy his discovery obligations, which is necessary to permit J&J to identify facts and evidence in rebuttal. J&J objects to this Interrogatory insofar as it seeks information outside of J&J's possession, custody, or control. J&J also objects that the response to this Interrogatory may be the subject of expert testimony.

J&J reserves all rights to supplement the Response to this Interrogatory as discovery and other fact-finding continues.

RELATOR'S INTERROGATORY #25

If you contend that Defendants' exclusion of generic competitors through the fraud alleged in the Complaint, which enabled Defendants to continue to charge monopoly prices for Zytiga, was not material to any decision by the government or Plaintiff States to pay or reimburse for Zytiga, please state all the legal and factual bases for such belief or contention.

RESPONSE TO INTERROGATORY #25

J&J objects to the terms "exclusion," "generic competitors," "fraud alleged in the Complaint," "monopoly prices," "material," and "decision" as undefined, vague, ambiguous, overbroad, unduly burdensome, and not described with reasonable particularity. J&J objects to this Interrogatory to the extent it calls for a legal conclusion in order to either respond or to determine whether any information is responsive. J&J objects to this Interrogatory to the extent it assumes facts and conclusions not established by the record. J&J further objects that this Interrogatory is premature and an improper contention request insofar as fact discovery is ongoing, expert discovery has not yet begun, Relator bears the burden of proof, and he has yet to satisfy his discovery obligations, which is necessary to permit J&J to identify facts and evidence in rebuttal. J&J further objects that the response to this Interrogatory may be the subject of expert testimony.

J&J reserves all rights to supplement the Response to this Interrogatory as discovery and other fact-finding continues.

Dated: March 25, 2024

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